MEMORANDUM OF UNDERSTANDING

Between

Shri B. M. Kankanawadi Ayurved Mahavidyalaya,

A Constituent Unit Of

KLE Academy of Higher Education & Research

(DEEMED-TO-BE-UNIVERSITY)

Belagavi, Karnataka.

and

KLE Dr. M. S. Sheshgiri College of Engineering And Technology, Belagavi, Karnataka.

For

Research, Training programs, Collaborative programs on Education, Faculty & Students Exchange

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ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Memorandum of Understanding between Shri B M Kankanawadi Ayurved Mahavidyalaya, a constituent unit of KLE Academy of Higher Education & Research (Deemed-To-Be-University) Belagavi, Karnataka and KLE Dr. M. S. Sheshgiri College of Engineering and Technology, Belagavi.

This Memorandum of Understanding (MoU) is executed on 13th day of April 2018 by and between Shri B M Kankanawadi Ayurved Mahavidyalaya, a constituent unit of KLE Academy of Higher Education & Research (Deemed-To-Be-University) Belagavi-590003 Karnataka, a premier institute having its place of activity in Belagavi, (here after referred as '**KLE BMK**', which expression shall, unless repugnant to the subject or thereof, be deemed to include and mean to its nominees, successors and permitted substitutes or assigns) on another PART either or both of which may be referred to as a "party" or the "Parties" respectively as the context demands with KLE Dr. M. S. Sheshgiri College of Engineering and Technology, Belagavi-590008 Karnataka (here in after referred as **KLE MSSCET**).

Background:

KLE Academy of Higher Education & Research Belagavi, Karnataka is Declared as Deemed-to-be-University U/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9.19/2000-U.3(A), Re-accredited (2nd cycle) as 'A' Grade by NAAC and placed in Category 'A' by MHRD Government of India. KLE Ayurveda Hospital & Medical Research Center has been accredited by NABH, the first Ayurvedic institute to get NABH accreditation in Karnataka. Shri BMK Ayurveda Mahavidyalaya is established in 1933 and is a constituent Institution of KLE Academy of Higher Education & Research (Deemed-To-Be-University) Belagavi, Karnataka. It has been recognized by CCIM for 11 PG departments with 65 seats and 100 UG seats. It is also conducting PhD program in Ayurveda and Interdisciplinary areas of

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

KAHER PG certificate programs on various domains like Vajeekarana, Ksharasutra, Panchakarma, Herbal Drug Research, Ayurgenomics etc. It has good infrastructure for teaching as well as research. Its Central Research facility has been approved as DTL for ASU drugs by AYUSH, Govt. of Karnataka. DAME has been recognized by CCIM as Regional Teacher Training center. KLE Dr. M. S. Sheshgiri college of Engineering and Technology, Belagavi-590008, Karnataka established in 1979. The institute is recognized by All India council for Technical Education, New Delhi and affiliated to Visvesvaraya Technological University, Belagavi. This is one of the premier technical institute in North Karnataka. It is under the ambit of Karnataka Lingayat Education Society, Belagavi. Four UG Programs Civil Engineering, Mechanical Engineering, Electronics and Communication Engineering and Computer Science Engineering are accredited by National Board of Accreditation (NBA), New Delhi for 3 years. The KLE MSSCET is recognized under section 2(f) of UGC Act 1956. KLE MSSCET is a self- financing and ISO-9001: 2015 certified institute. The institution presently offers seven undergraduate and 5 postgraduate programmes in engineering and technology in addition to MBA and MCA programmes. 11 Departments of this institution are recognized as research centers by Visvesvaraya Technological University, Belagavi.

Under this Memorandum of Understanding, the two institutions will proceed to implement the following endeavors and exchanges of materials and personnel.

ARTICLE I: OBJECTIVE

The objective of this agreement is to develop scientific, academic and educational co-operation, establish a collaborative program in research between two institutes and cooperate in their mutual interest for a range of higher educational and scientific activities. The main intent of this initiative is to perform collaborative research project in developing Technology in the field of

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Prof. Dr. V.A.KOTHIWALE
Registrar
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Indian system of Medicine (Ayurveda) and Inter Disciplinary activities between the two Institutions.

ARTICLE II: AREAS OF COOPERATION

Cooperation shall be carried out, subject to availability of funds and the approval of the competent authority of **'KLE BMK' and 'KLE MSSCET'**, through such activities or programs as:

Utilization of research facilities and joint research activities:

- Faculty and students of both institutions will be allowed, with prior permission, to utilize the research facilities of the institutions by prescribed nominal fee.
- Both will promote and facilitate inter-institutional, interdisciplinary research and collaborative research projects by faculty and students of the institutions. Short term research projects, summer research projects etc will be allowed.

Continuation of PG/Ph. D. thesis activities:

Students of both institutes will be allowed to have extension of their dissertation / thesis activities utilizing facilities and expertise in these institutions.

Teaching Content development:

- Both the institute will work to create better teaching methodology, evaluation methods, feedback methods, multimedia utilization in teaching, and simulations etc for Medical and Engineering aspects.
- Exchange of academic materials and other information
- The terms of such mutual cooperation and necessary budget for each specific program and activity that is implemented under the terms of this MoU. Each institute will designate a Liaison Officer to develop and coordinate specific activities or programs.

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ARTICLE III: FINANCIAL ARRANGEMENTS

- The financial arrangements to cover expenses for the identified research activities undertaken within the framework of this Memorandum of Understanding shall be mutually agreed upon by both the Parties on a case-by-case basis subject to availability of funds.

ARTICLE IV: PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

(a) The protection of intellectual property rights shall be enforced in conformity with the national laws, rules and regulations.

(b) Notwithstanding anything in paragraph (a) above, the intellectual property rights in respect of any technological development and any products / services development are carried out.

(i) Jointly by the parties or research results obtained through the joint activity effort by the Parties, shall be jointly owned by the Parties in accordance with the terms to be mutually agreed upon

(ii) Solely and separately by the Party or the research results obtained through the sole and separate effort of the Party, shall be solely owned by the Party concerned.

(iii) The terms and conditions in the execution of the research projects shall be decided on case to case basis.

ARTICLE V: CONFIDENTIALITY

A. Each Party undertakes to observe the confidentiality and secrecy of documents, information and other data received from, or supplied to, the other Party during the period of the implementation of this Memorandum of Understanding or any other agreements made pursuant to this Memorandum of Understanding

ATTESTED

PROF. V. V. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

B. Both Parties agree that the provisions of this Article shall continue to be binding between the Parties notwithstanding the termination of this Memorandum of Understanding.

ARTICLE VI: SETTLEMENT OF DISPUTES

Any difference or dispute between the Parties concerning the interpretation and/or implementation and/or application of any of the provision of this Memorandum of Understanding shall be settled amicably through mutual consultation and/or negotiation between the Parties. In case, the dispute occurred between both the parties and if the same is not resolved through negotiation or by adopting amicable measures, in that case the matter will be settled through Arbitration and the Arbitrator will be appointed with the mutual consent of both the parties.

ARTICLE VII: ENTRY INTO FORCE, DURATION AND TERMINATION

This understanding shall come into force and take effect from the date first written above and shall be valid for a period of FIVE (5) YEARS and may be renewed thereafter by the parties upon mutual consent.

This understanding may be terminated by either party by providing 90 (ninety) days written notice to the other party before the beginning of academic year, and the termination would be effective at the end of the notice period.

And the termination of the Understanding shall be on the understanding that students / faculty who have already enrolled in any of the courses / research programs as at the time of termination shall remain entitled to complete their respective courses / research programs and be eligible to appear assessment conducted by the **'KLE BMK'** and **'KLE MSSCET'** conduced to obtain an award. The obligation of the parties shall continue to be in force during such period, notwithstanding any termination of the Understanding.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Now this MOU Witnesses as follows the Roles and Responsibilities of Either Party:

a) Common Responsibilities

i. Students/ faculty have to pay the prescribed fee for the facilities they have used.

ii. Both the institutes have to facilitate for easy exchange programs and collaborative work. Administrative hurdles to be cleared at higher level by clear transparent methodology.

iii. Periodic meeting of co-ordinators. should be arranged to have collaboration and co-operation among faculty of two institutes.

iv. Both parties understand that all financial arrangements and will have to be negotiated and will depend on the availability of funds.

b) Roles & Responsibilities of KLE Shri B.M.Kankanawadi Ayurved Mahavidyalaya a constituent unit of KLE Academy of Higher Education & Research (Deemed-to-be-University) Belagavi.

a. Identifying the areas of technology implementation conceptualization

b. Providing preliminary basic data and necessary medical information

c. Suggesting necessary modifications and new requirements.

c) Roles & Responsibilities of KLE Dr. M. S. Sheshgiri College of Engineering and Technology, Belagavi.

a. To provide engineering and technological knowledge.

b. Designing and development of equipments / instruments /gadgets/ software for Indian System of Ayurvedic Therapy.

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

c) Miscellaneous:

- A coordination committee consisting of the following will monitor the academic and collaborative research programs and all related operational activities.
- Principal, Shri B. M. Kankanawadi Ayurved Mahavidyalaya, A Constituent unit of KAHER Belagavi, Karnataka.
- Principal, KLE Dr. M. S. Sheshgiri College of Engineering and Technology, Belagavi.
- Dr. Anil Koralli, Co-ordinator, Dr. A.P.J Abdul Kalam AYURTECH Incubation Centre. Co-ordinator, Dr. Raviraj Havaldar, Professor and Head, Dept of Biomedical Engineering, KLE Dr. M. S. Sheshgiri College of Engineering and Technology, Belagavi

d) Coordinators of each center

At KAHER Shri BMK Ayurveda Mahavidyalaya, Principal will oversee the implementation of the Memorandum of Understanding.

At KLE Dr. M. S. Sheshgiri College of Engineering and Technology, Belagavi, Principal will oversee the implementation of the Memorandum of Understanding.

Any variation or amendment or addition of / to this Understanding shall be mutually agreed to in writing and executed by or on behalf of each of the parties, **'KLE BMK'** and **'KLE MSSCET'**

This Understanding represents the entire understanding as to the subject matter hereof and supersedes any prior understanding between the parties on the subjects matter hereof.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

In witness whereof, the parties hereto have executed this understanding as of the date first above mentioned.

Sealed & signed for and on behalf of

Registrar,
KLE Academy of Higher Education & Research (Deemed-To-Be-University), Belagavi, Karnataka, 590003

REGISTRAR
KLE Academy of Higher Education and Research, BELAGAVI

in the presence, of

PRINCIPAL
Shri B. M. Kankanawadi Ayurved Mahavidyalaya
A Constituent Unit of KAHER
Shahapur, BELAGAVI-1

in the presence, of

(Dr. K. Anil)

Sealed & signed for and on behalf of

Principal,
KLE Dr. M. S. Sheshgiri College of Engineering and Technology, Belagavi, Karnataka, 590008

PRINCIPAL
KLE Dr. M. S. Sheshgiri College of Engg. & Tech.
BELAGAVI

in the presence, of

(Dr. S. A. Joshi)

in the presence, of

(Dr. R. H. Halvaldar)

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

KLE College of Pharmacy
A Constituent Unit of
KLE Academy of Higher Education and Research
(Deemed-to- be University established u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi – 590 010, Karnataka, India
(Recognized by PCI, AICTE)
Phone: 0831-2471399 Fax: 0831-2472387 Web: http://www.klepharm.edu E-mail:principal@klepharm.edu

Ref. No. KLE / COP/ Date: 12/2/2018

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MoU) between **Empree Medicaments Pvt. Ltd., Plot No. 99 C & D, KIADB Industrial estate, Honaga, Belagavi- 591 113, Karnataka, India**represented by Shri. AmritKhoda, CEO, Empree Medicaments Pvt. Ltd., Belagavi of the One Part.

And

KLE College of Pharmacy, Belagavi, established in 1985 and engaged in teaching, training and research in Pharmaceutical Science (herein after called "the Institute") represented by Dr. B. M. Patil, Principal KLE College of Pharmacy, Belagavi, of the One Part.

Aims and Objectives of the MoU

1) By entering into this MoU the Institute and Empree Medicaments Pvt. Ltd.,Belagaviagree to set up a frame work to encourage and develop collaboration between Empree Medicaments Pvt. Ltd.,Belagaviand the Institute in the areas of mutual interest in the field of Pharmaceutical Science.

2) The initial specific objectives between the parties are as under:

- To raise the research profile of both the Institute and Empree Medicaments Pvt. Ltd.,Belagaviby developing collaborative research projects that utilizes the expertise and the environment of work both theEmpree Medicaments Pvt. Ltd.,Belagaviand the Institute.
- To provide an opportunity to students of the Institute to learn and develop research skills.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

KLE College of Pharmacy
A Constituent Unit of
KLE Academy of Higher Education and Research
(Deemed–to- be University established u/s 3 of the UGC Act, 1956)
Accredited'A' Grade by NAAC (2nd Cycle)Placed inCategory 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi – 590 010, Karnataka, India
(Recognized by PCI, AICTE)
Phone: 0831-2471399 Fax: 0831-2472387 Web: http://www.klepharm.edu E-mail:principal@klepharm.edu

Ref. No. KLE / COP/ Date:

3) The parties shall not at any time during or after the term of this MoU, divulge, or allow to be divulged, to any person, any confidential information(including, but not limited to, any information relatingto the accounts, finance, contractual arrangement, products, business or affairs of the parties) unless the said information comes in public domain without breach by either party.

4) This MoU shall be in operation for a period of **FIVE** years from the date of signing.

12/12/2018

Signed on behalf of
KLE College of Pharmacy, Belagavi
Nehru Nagar, Belagavi – 590 010
Karnataka, India

PRINCIPAL
KLE College of Pharmacy
BELAGAVI - 10.

Signed on behalf of
Empree Medicaments Pvt. Ltd.,
Plot No. 99 C &D, KIADB Industrial estate,
Honaga, Belagavi - 591 113, Karnataka,
India

ATTESTED

Dr. [illegible] KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Empree Medicaments (India) Pvt. Ltd
Factory : 99, C&D, KIADB Industrial Estate, Honaga, Belgaum-591 113
Telephone : 91-831-2414111/12, Fax : 91-831-2414305
Email : empreebgm@gmail.com.

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MoU) between **Empree Medicaments (I) Pvt. Ltd., Plot No. 99 C & D,KIADB Industrial estate, Honaga, Belagavi- 591 113, Karnataka, India** represented by Shri. Amrit Khoda, CEO, Empree Medicaments Pvt. Ltd., Belagavi of the One Part.

And

KLE College of Pharmacy, Belagavi, established in 1985 and engaged in teaching, training and research in Pharmaceutical Science (herein after called "the Institute") represented by Dr. B. M. Patil, Principal KLE College of Pharmacy, Belagavi, of the One Part.

Aims and Objectives of the MoU

2) By entering into this MoU the Institute and Empree Medicaments (I) Pvt. Ltd., Belagavi agree to set up a frame work to encourage and develop collaboration between Empree Medicaments Pvt. Ltd., Belagavi and the Institute in the areas of mutual interest in the field of Pharmaceutical Science.

2) The initial specific objectives between the parties are as under:

- To raise the research profile of both the Institute and Empree Medicaments (I) Pvt. Ltd., Belagavi by developing collaborative research projects that utilizes the expertise and the environment of work both the Empree Medicaments (I) Pvt. Ltd.,Belagavi and the Institute.
- To provide an opportunity to students of the Institute to learn and develop research skills.
- To exploit the synergy arising from joint initiatives to improve student training.

Contd.....2....

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Empree Medicaments (India) Pvt. Ltd
Factory : 99, C&D, KIADB Industrial Estate, Honaga, Belgaum-591 113
Telephone : 91-831-2414111/12, Fax : 91-831-2414305
Email : empreebgm@gmail.com.

3) The parties shall not at any time during or after the term of this MoU, divulge, or allow to be divulged, to any person, any confidential information(including, but not limited to, any information relatingto the accounts, finance, contractual arrangement, products, business or affairs of the parties) unless the said information comes in public domain without breach by either party.

4) This MoU shall be in operation for a period of FIVEyears from the date of signing.

12/2/2018

Signed on behalf of
KLE College of Pharmacy, Belagavi
Nehru Nagar, Belagavi – 590 010
Karnataka, India

PRINCIPAL
KLE College of Pharmacy
BELAGAVI - 10.

Empree
Medicaments (India) Pvt. Ltd.
DIRECTOR

Signed on behalf of
Empree Medicaments (I) Pvt. Ltd.,
Plot No. 99 C &D, KIADB Industrial estate,
Honaga, Belagavi - 591 113,
Karnataka, India

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

Date: 13.08.2018

13/8/18 To / Uckt

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. NILESH JAIN a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 100 hours training from 26th June 2018 to 26th July 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing him Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar

HICURE PHARMACEUTICALS PRIVATE LIMITED

Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Santosha Nandikoppa a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 In Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing him Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadasakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

12/9/18
To, Visit

Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Akshayakumar Hallgeri a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing him Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356217. Fax : 0836-4253632.
E-mail : hicure1@gmail.com www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

Date: 06.08.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. SURAJMANJUSHREE KONCHIGERI a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 100 hours training from 26th June 2018 to 26th July 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing him Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283541.
Admin. Office : Chandrika, Chilaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

K.L.E. SOCIETY'S

KLE COLLEGE OF PHARMACY

Vidyanagar, HUBLI-580 031 (Karnataka)
Recognised by Government of Karnataka & Affiliated to Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore
Approved by Pharmacy Council of India (PCI) & All India Council for Technical Education (AICTE), New Delhi
B. Pharm. Course Accredited by National Board of Accreditation, AICTE, New Delhi

ಕೆ.ಎಲ್.ಇ. ಸಂಸ್ಥೆಯ
ಔಷಧ ವಿಜ್ಞಾನ ಮಹಾವಿದ್ಯಾಲಯ, ವಿದ್ಯಾನಗರ, ಹುಬ್ಬಳ್ಳಿ-580 031

To,

Ref. No. KLESCOP/HBL/ವಿಶ್ಲ/2017-18/610 Date : 15/3/2018

The Plant Manger,
Hicure Pharma Pvt. Ltd.,
Kadankoppa, Kalagatagi road,
Kalagatagi.

Sub: Permission to visit your esteemed industry by the final year B.Pharm. Students ..... reg.

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Sir,

We are pleased to inform you that, we are running B.Pharm. courses since 1991 & 1999 respectively. These courses are approved by AICTE & PCI, New Delhi and Institution is reaccredited by NBA, AICTE, New Delhi. As per the regulations of B.Pharm. Course, the students studying in Final year B.Pharm. are required to visit several Pharmaceutical manufacturing units and laboratories as supplement to their academic training and they are required to submit the report to the Head of the institution where he/she is studying.

In this context, our Final year B.Pharm. students intend to visit your esteemed industry in third week of March, 2018. We will be grateful to you, if permit us to visit your industry. I am confident that your good self will permit us and widen the knowledge.

Hoping for your early and favorable reply.

Thanking you,

KLE COLLEGE OF PHARMACY HUBBALLI 580031

Yours faithfully,

PRINCIPAL

Note : 45 students and 2 staff members will be visiting in one batch or as per your convenience.

ATTESTED

✆ : Off. : 0836-2373174, Fax : 0836-2371694, 2371048
E-mail : principal@klescoph.com Website: http://www.klescoph.org

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

16/8/18 TO, GUIDE

Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Praveen Kumar Gandhudi a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 in Parentral Formulations and Quality Control Section as per the University Syllabys.

Wishing him Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadambappa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-233543.
Admin. Office : Chandrika, Chitaguppi Park, Plain Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Totl Manjunath a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing him Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

12/8/18 for Hicure Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms. Sakshi a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing her Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

17/7/18

Date: 02.07.2018

To, Whom

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms. Maheswari Basavraj Hireholi a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing her Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

HICURE PHARMACEUTICALS PRIVATE LIMITED

Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms. Prabha B Angadi a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing her Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237, Fax : 0836-4253612.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

HICURE PHARMACEUTICALS PRIVATE LIMITED

Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms. Sukanya Palotl a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 In Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing her Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadamaloppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-281543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4251632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

HICURE PHARMACEUTICALS PRIVATE LIMITED

Date: 02.07.2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Kartik Ishwar Mundaragi a student of Final Year B. Pharma College of Pharmacy, Hubli, Karnataka, has successfully completed 120 hours training from 1st June 2018 to 30th June 2018 in Parentral Formulations and Quality Control Section as per the University Syllabus.

Wishing him Success.

For Hicure Pharmaceuticals Pvt Ltd

Authorised Signatory.

Regd. Office & Factory : Hubli-Karwar National Highway, Kadanakoppa, Tq. Kalghatgi, Dist. Dharwad. (Karnataka) Telefax : 08370-283543.
Admin. Office : Chandrika, Chitaguppi Park, Pinto Road, HUBLI-580 020. Dist. Dharwad. (Karnataka) Tel : 0836-2356237. Fax : 0836-4253632.
E-mail : hicure1@gmail.com Website : www.hicure.co.in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

INDIA NON JUDICIAL

Government of Karnataka

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सत्यमेव जयते

Certificate No.	:	IN-KA55053755747760
Certificate Issued Date	:	15-May-2018 12:08 PM
Account Reference	:	SHCIL (FI)/ ka-shcil/ SHCIL BELGAUM/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKA-SHCIL56245713686774Q
Purchased by	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Description of Document	:	Article 12 Bond
Description	:	MEMORANDUM OF UNDERSTANDING
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Second Party	:	SOUTHERN CROSS UNIVERSITY QUEENSLAND 4225AUSTRALIA
Stamp Duty Paid By	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatory
For Stock Holding Corporation of India Ltd
No.1, Basavakrupa, Opp. Civil Hospital
Near Hansraju Super Market,
Club Road, BELGAUM- 590001

Please write or type below this line

MEMORANDUM OF UNDERSTANDING
Between
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
A deemed to be university under u/s 3 of the UGC Act, 1956 vide
Government of India notification No. 9-19/2000-U.3A
Belagavi, Karnataka, India
AND
SOUTHERN CROSS UNIVERSITY,
Act 1993 Gold Coast campus B-7.21Southern Cross
Drive Bilinga Queensland 4225, Australia,

Statutory Alert

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

Between

SOUTHERN CROSS UNIVERSITY

AND

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

A deemed to be university under u/s 3 of the UGC Act, 1956 vide Government of India notification No. 9-19/2000-U.3A
Belagavi, Karnataka, India

The KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER) Belagavi, Karnataka, India and SOUTHERN CROSS UNIVERSITY (SCU), a body corporate incorporated under the Southern Cross University Act 1993 Gold Coast campus B-7.21 Southern Cross Drive Bilinga Queensland 4225, Australia, recognized the benefits to their respective universities from the establishment of collaborations and proceed to have a memorandum of understanding (MoU). Both the independent institutions are committed to mutual and common goals of generating new knowledge towards improvement of science to betterment of the society we serve.

PREAMBLE

KAHER, being the centre of excellence has been positioned as the 3rd Best University at State Level among the Universities in Karnataka by Karnataka State Universities Ranking Framework (K- SURF) and 14th rank among all Indian Universities under Teaching Learning & Resources (TLR) category. The University adjudged as the fourth cleanest campus in the country in a contest organized by the Ministry of Human Resource Development. The University is re-accredited with "A" grade by NAAC in 2015 and is placed in category "A" by MHRD, Govt of India

The Institute of Nursing Sciences was established in May 1987 and recognized as one of the top institution in India. All the courses offered by institution are recognized by apex bodies like Indian Nursing Council, Karnataka Nursing Council and Govt of Karnataka. The institution attached to the own parent hospital i.e. KLES Dr.Prabhakar Kore Hospital & MRC with 2400 bed strength and 256 ICU beds accredited with NABH safe I & NABL accredited laboratories, KLES Belgaum Cancer Hospital & KLES Centenary Charitable Hospital.

Southern Cross University is a relatively young (est. 1994), regional University in Australia, which has a reputation for conducting high quality teaching and research. There are three main campuses: Gold Coast (Queensland), Lismore and Coffs Harbour (NSW), with branch campuses in Sydney, Perth and Melbourne as well as tailored online delivery modes. According to 2017 Times Higher Education rankings, Southern Cross University is one of the Asia-Pacific's Top 100 Universities and one of the world's Top 50 Generation Y Universities.

ATTESTED

Prof. Dr. V.A. KOTTIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Teaching and research activities span a range of disciplines which fall broadly into these groupings: arts and social science, law and justice, Indigenous studies, education, health (eg.; psychology, nursing, podiatry), engineering, business, tourism, and environmental and agricultural science (eg.; marine, plant, geoscience). The Excellence in Research Australia (ERA) 2015 assessment rated twenty-four discipline areas as performing 'at or above world standard'.

The respective universities jointly recognize this MoU to mutually cooperate in the area of Health Education and Research including allied health sciences.

PURPOSE / OBJECTIVE

The Primary purpose of this MoU is to discuss the development of a **"Communication in Leadership Program"** for Registered Nurses and undergraduate students in India. The MoU shall enable the parties to discuss the terms of a potential cooperative relationship between the parties including in relation to collaborative research.

Both universities agree to discuss collaborative activities in academic areas of mutual interest and as equal partners with reciprocity. All educational events are expected to reflect the faculty members' areas of research and expertise.

The development and implementation of specific activities based on this MoU shall be negotiated and agreed between individual faculty members through the Deans or Heads of Department and included in a legally binding agreement.

The MOU is agreed on the basis of cooperation between the Universities and includes, but not limited to the following options:

a. Exchange of the faculty members and research scholars between the Universities
b. Exchange of students based on the project and research needs.
c. Jointly apply for the research funds to conduct collaborative research projects
d. Conducting colloquiums
e. Exchange of academic/research information and related materials to facilitate joint publications by collaborating faculty members
f. Promoting any related academic activities based on mutual agreement

Both Universities agree to carry out the above mentioned activities in accordance with laws and regulations of respective countries after full consultation and approvals.

- This Memorandum does not create any legally binding relationship between the parties, or confer any legal rights or impose any legal obligations on either of them.
- If the parties need to exchange or share any information that is confidential, then the parties will enter into appropriate non-disclosure agreements to protect the confidentiality and integrity of that information.
- Any public announcements or statements (including to the media) about any of the matters dealt with in

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

this Memorandum will first be agreed between the parties before their release or publication.

The term of this MoU shall be valid for the period of three years commencing from the date of signature hereof. The agreement can be extended for further terms on mutual agreement. This agreement may be terminated by giving 3 months prior notice from either party.

In witness whereof, the parties have executed this documented on the April 2018.

REGISTRAR
KLE ACADEMY OF HIGHER EDUCATION
AND RESEARCH, BELAGAVI.

Registrar
KLE Academy of Higher Education and Research Belagavi,
Karnataka, India

Signed for and on behalf of Southern Cross University by its duly Authorised Representative:
Signature: Prof Susan Nancarrow
Position: Deputy Vice Chancellor Research
Date: 9 April 2018

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

INDIA NON JUDICIAL

Government of Karnataka

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Certificate No.	:	IN-KA55502894938469Q
Certificate Issued Date	:	15-May-2018 12:05 PM
Account Reference	:	SHCIL (FI)/ ka-shcil/ SHCIL BELGAUM/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKA-SHCIL56253966842306Q
Purchased by	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Description of Document	:	Article 12 Bond
Description	:	MEMORANDUM OF UNDERSTANDING
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Second Party	:	CHITWAN MEDICAL COLLEGE SCHOOL NSG CHITWAN NEPAL
Stamp Duty Paid By	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatory
For Stock Holding Corporation of India Ltd
No.1, Basavakrupa, Opp. Civil Hospital
Near Hansraju Super Market,
Club Road BELGAUM- 590001

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

Between

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

A deemed to be university under u/s 3 of the UGC Act, 1956 vide Government of India notification No. 9-19/2000-U.3A

Belagavi, Karnataka, India

AND

CHITWAN MEDICAL COLLEGE, SCHOOL OF NURSING,

[Affiliated to Tribhuvan University], Kailashnagar, Bharatpur 5, Chitwan, Nepal

Statutory Alert

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

Between

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

A deemed to be university under u/s 3 of the UGC Act, 1956 vide
Government of India notification No. 9-19/2000-U.3A
Belagavi, Karnataka, India

AND

CHITWAN MEDICAL COLLEGE, SCHOOL OF NURSING,

[Affiliated to Tribhuvan University], Kailashnagar, Bharatpur 5, Chitwan, Nepal

The KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER) Belagavi, Karnataka, India and CHITAWAN MEDICAL COLLEGE SCHOOL OF NURSING, (Affiliated to Tribhuvan University), Kailashnagar, Bharatpur 5, Chitwan, Nepal, recognised the benefits to their respective universities from the establishment of collaborations and proceed to have a memorandum of understanding (MoU). Both the independent institutions are committed to mutual and common goals of generating new knowledge towards improvement of science to betterment of the society we serve.

PREAMBLE

KAHER, being the centre of excellence has been positioned as the 3rd Best University at State Level among the Universities in Karnataka by Karnataka State Universities Ranking Framework (K-SURF) and 14th rank among all Indian Universities under Teaching Learning & Resources (TLR) category. The University adjudged as the fourth cleanest campus in the country in a contest organized by the Ministry of Human Resource Development. The University is re-accredited with "A" grade by NAAC in 2015 and is placed in category "A" by MHRD, Govt. of India

The Institute of Nursing Sciences was established in May 1987 and recognized as one of the top institution in India. All the courses offered by institution are recognized by apex bodies like Indian Nursing Council, Karnataka Nursing Council and Govt. of Karnataka. The institution attached to the own parent hospital i.e. KLES Dr.Prabhakar Kore Hospital & MRC with 2400 bed strength and 256 ICU beds accredited with NABH safe 'I' & NABL accredited laboratories, KLES Belgaum Cancer Hospital & KLES Centenary Charitable Hospital.

ATTESTED

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PREAMBLE of CMC

Chitwan Medical College (CMC) is situated in the heart of Chitwan District, Nepal. It was established in the year 2006. CMC is built over an area of 20 biga of land in Kailashnagar (approx. 8kms from city). The parent hospital is situated in Bharatpur city which is built as per international guidelines and achieved Best Teaching Hospital by ISO.

The School of Nursing Sciences was established in October 2006 under the affiliation to Tribhuvan University, Nepal and Nepal Nursing Council. The school started initially with PBBN program and then went on to start B.Sc. Nursing and Master Nursing programs subsequently. The institution attached to the own parent hospital i.e. Chitwan Medical College Teaching Hospital with 751 bed strength recognized by ISO 2001 certification.

The respective universities jointly recognize this MoU to mutually cooperate in the area of Health Education and Research including allied health sciences.

PURPOSE / OBJECTIVE

The Primary purpose of this MoU is for the development of ongoing framework for student and staff elective placement and exchange program to promote effective, safe, skillful & knowledgeable nursing practice.

The MoU shall formerly set out the term of cooperative relationship between the parties establish their respective roles and facilitate the function of each party in relation to collaborative research.

Both universities s agree to develop collaborative activities in academic areas of mutual interest and as equal partners with reciprocity. All educational events are expected to reflect the faculty member's areas of research and expertise.

The development and implementation of specific activities based on this MoU shall be negotiated and agreed between individual faculty members through the Deans or Heads of Department.

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

The MOU is agreed on the basis of cooperation between the Universities and includes, but not limited to the following options:

1. Elective placement and exchanges of faculty and students
2. Co-author and collaborate in areas of research interest
3. Conducting colloquiums
4. Strengthen midwifery practices by organization of hands on skill training programs
5. As a pathway to Ph.D program – By facilitating student from Chitwan Campus to pursue Ph.D at KAHER campus.
6. Exchange of academic/research information and related materials to facilitate joint publications by collaborating faculty members
7. Promoting any related academic activities based on mutual agreement

Responsibilities of KAHER Institute of Nursing Sciences, Belagavi, Karnataka, India and Chitwan Medical College School of Nursing, [Affiliated to Tribhuvan University], Kailashnagar, Bharatpur 5, Chitwan, Nepal will:

1. Arrange local logistics and local travel, during student and faculty exchange program
2. Arrangement of food and accommodation for students and faculty within minimal cost
3. Organizing the lectures and clinical placements for students
4. Coordinating with resource persons and participating Institution.
5. Providing technical inputs in all phases of MOU.
6. Flight costs will not be provided to faculty and students.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

TERMS OF AGREEMENT

Both Universities agreed to carry out the above mentioned activities in accordance with laws and regulations of respective countries after full consultation and approvals.

The term of this agreement shall be valid for the period of three years commencing from the date of signature hereof. The agreement can be extended for further terms on mutual agreement. This agreement may be terminated by giving 6 months prior notice from either parties.

In this witness whereof, the parties have excluded this documented on May 2018

Prof. Dr. Harish Chandra Neupane
Chairman & Managing Director
Chitwan Medical College
Bharatpur, Chitwan, Nepal

Registrar
KLE Academy of Higher Education and Research
BELAGAVI, KARNATAKA, INDIA

Prof. Dr. Harishchandra Neupane
Chairman & Managing Director
Chitwan Medical College
Bharatpur, Nepal

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI.

Witness 1:

Witness 1:

Dean, Faculty of Nursing & Principal
Institute of Nursing Sciences, KAHER
Belagavi, Karnataka, India

Dean, Faculty of Nursing
Principal, Institute of Nursing Sciences
KAHER, BELAGAVI

Mr.Siddeshwar Angadi
Vice Principal & Associate Professor
School of Nursing CMC
Bharatpur, Nepal.

VICE CHANCELLOR
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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सत्यमेव जयते

Certificate No.	:	IN-KA60496465982241Q
Certificate Issued Date	:	23-May-2018 12:01 PM
Account Reference	:	SHCIL (FI)/ ka-shcil/ SHCIL BELGAUM/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKA-SHCIL658972683518430
Purchased by	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Description of Document	:	Article 4 Affidavit
Description	:	MEMORANDUM OF UNDERTAKING
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Second Party	:	DEBRE BERHAN UNIVERSITY DEBRE BERHAN ETHIOPIA
Stamp Duty Paid By	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatory
For Stock Holding Corporation of India Ltd
No.1, Basavakrupa, Opp. Civil Hospital
Near Hansraju Super Market,
Club Road, BELGAUM- 590001

Please write or type below this line

MEMORANDUM OF UNDERSTANDING
Between
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
A deemed to be university under u/s 3 of the UGC Act, 1956 vide
Government of India notification No. 9-19/2000-U.3A
Belagavi, Karnataka, India
AND
DEBRE BERHAN UNIVERSITY, Debre Berhan, Ethiopia
DBU established under the Federal Democratic Republic of Ethiopia,
Proclamation No. 691/2010, and
Article 5 (1) of the higher education proclamation No. 650/2009.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

Between

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

A deemed to be university under u/s 3 of the UGC Act, 1956 vide
Government of India notification No. 9-19/2000-U.3A
Belagavi, Karnataka, India

AND

DEBRE BERHAN UNIVERSITY, Debre Berhan, Ethiopia

DBU established under the Federal Democratic Republic of Ethiopia,
Proclamation No. 691/2010, and
Article 5 (1) of the higher education proclamation No. 650/2009.

The KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER) Belagavi, Karnataka, India and Debre Berhan University, Debre Berhan Town, Ethiopia recognised the benefits to their respective universities from the establishment of collaborations and proceed to have a Memorandum of Understanding (MoU). Both the independent institutions are committed to mutual and common goals of generating new knowledge towards improvement of science to betterment of the society we serve.

PREAMBLE

KAHER, being the centre of excellence has been positioned as the 3rd Best University at State Level among the Universities in Karnataka by Karnataka State Universities Ranking Framework (K-SURF) and 14th rank among all Indian Universities under Teaching Learning & Resources (TLR) category. The University adjudged as the fourth cleanest campus in the country in a contest organized by the Ministry of Human Resource Development. The University is re-accredited with "A" grade by NAAC in 2015 and is placed in category "A" by MHRD, Govt. of India

The Institute of Nursing Sciences was established in May 1987 and recognized as one of the top institution in India. All the courses offered by institution are recognized by apex bodies like Indian Nursing Council, Karnataka Nursing Council and Govt. of Karnataka. The institution attached to the own parent hospital i.e. KLES Dr.Prabhakar Kore Hospital & MRC with 2400 bed strength and 256 ICU beds accredited with NABH safe 'I' & NABL accredited laboratories, KLES Belgaum Cancer Hospital & KLES Centenary Charitable Hospital.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PREAMBLE of DBU

Debre Berhan University, which is a 10 year young university, was established in the 600 years old historical town- Debre Berhan – a town situated in North Shoa Zone, Amhara Region. It is 130 km away from Addis Ababa in the north. The foundation stone was laid down on 9th May 2005 G.C by her Excellency w/ro Genet Zewdie, the then Minister of Ministry of Education of the Federal Democratic Republic of Ethiopia. DBU stood 3rd in 2015, 1st in 2016, and 2nd in 2017 among the second generation universities, for its overall activities in the teaching-learning activities, research and community service. For the achievements done so far, certificates were given to the University for recognition of excellence form the Ministry of Education.

The enrolment has significantly increased to about 30,000 regular, extension, summer, and distance students who joined into 49 departments in the undergraduate /programs under 10 colleges, 2 institutes and on 34 post graduate programs, along with 2 PhD programs. Currently, the university is staffed with around 1262 (first degree to third degree) academic staffs (about 480 are on study leave), about 1154 administrative staffs including technical workers. The institute of Medicine and Health Science comprises medicine and health Science College. The institute was set up in 2008, and it has medicine, nursing, health officer, midwifery, anaesthesia, surgical nursing, paediatrics' nursing, neonatal nursing programs, and master in public health.

PURPOSE / OBJECTIVE

The Primary purpose of this MoU is to **forge partnership so as to strengthen/complement one another in their efforts to deliver quality services in their areas of mandates and common interventions.**

The MoU shall formerly set out the term of cooperative relationship between the parties establish their respective roles and facilitate the function of each party in relation to collaborative research.

Both universities s agree to develop collaborative activities in academic areas of mutual interest and as equal partners with reciprocity. All educational events are expected to reflect the faculty member's areas of research and expertise.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

The development and implementation of specific activities based on this MoU shall be negotiated and agreed between individual faculty members through the Deans or Heads of Department.

The MOU is agreed on the basis of cooperation between the Universities and includes, but not limited to the following options:

1. Elective placement and exchanges of faculty and students
2. Co-author and collaborate in areas of research interest and community services
3. Conducting colloquiums, conferences, symposiums, workshops and seminars, etc.
4. Strengthen academic areas, namely nursing, midwifery, and public health practices by organization of hands on skill training programs
5. Exchange of academic/research information and related materials to facilitate joint publications by collaborating faculty members
6. Exchange of academic information, publications, best practices, pedagogical materials, library and documentations, etc.
7. Promoting any related academic activities based on mutual agreement
8. Any other collaborative efforts as may be determined by both parties.

Responsibilities of KAHER Institute of Nursing Sciences, Belagavi, Karnataka, India and Debre Berhan University, Debre Berhan Town, Ethiopia will:

1. Arrange local logistics and local travel, during student and faculty exchange program
2. Arrangement of food and accommodation for students and faculty within minimal cost
3. Coordinating with resource persons and participating Institution.
4. Providing technical inputs in all phases of MOU.
5. Flight costs will not be provided to faculty and students.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

TERMS OF AGREEMENT

Both Universities agreed to carry out the above mentioned activities in accordance with laws and regulations of respective countries after full consultation and approvals.

The term of this agreement shall be valid for the period of three years commencing from the date of signature hereof. The agreement can be extended for further terms on mutual agreement. This agreement may be terminated by giving 6 months prior notice from either parties.

In this witness whereof, the parties have excluded this documented on May 2018

Registrar
KLE Academy of Higher Education and Research
Belagavi, Karnataka, India

REGISTRAR
KLE Academy of Higher Education and Research
BELAGAVI

Witness 1: Sudha

Dean, Faculty of Nursing
Principal, Institute of Nursing Sciences,
KAHER, Belagavi
Dean, Faculty of Nursing & Principal
Institute of Nursing sciences, KAHER
Belagavi, Karnataka, India

Academic Vice President
Hailemariam Birke Andarge (PhD)
Dr. Hailemariam Birke
Academic Vice President of
Debre Berhan University,
Ethiopia

Witness 1:

Dr. Seid Mohammed, Ph.D.
Director of Foreign & Public Relations
Directorate

Dr. Seid Mohammed
Foreign & Public Relations
Director

ATTESTED

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MSAI and Exchanges

Medical Students Association of India was established in 2011 and has also been a member organization representing India at the International Federation of Medical Students' Associations (IFMSA) since 2012. In 2016, MSAI also became a part of the **world's largest student-run exchange program** that has conducted thousands of international exchanges since 1951. MSAI has conducted **over 200 exchanges** since 2016 with **over 50 countries** as a part of this program. IFMSA exchanges have received recognition from various international organizations like the World Federation of Medical Education (WFME), the World Organization of Family Doctors (WONCA), the Federation of European Neuroscience societies (FENS), European Society for Emergency Medicine (EuSEM), World Federation of Societies of Anaesthesiologists (WFSA) and International Federation of Gynaecology and Obstetrics (FIGO). Exchanges are broadly classified into Professional and Research exchanges.

KLE's Jawaharlal Nehru Medical College, Belagavi, has been one of our most important partners in making exchanges accessible to a larger number of students. With the help of their zealous students and supportive faculty, we have been able to host a number of students from across the world for the past two years.

Research Exchanges

A **four weeks long research project** that provides medical students with the opportunity to deepen their knowledge in a specific area of their interest. This program is usually supported by a medical school/university and is guided by a mentor who introduces the students to the basic principles of research, including literature review, data collection, scientific writing, laboratory work, statistics, and ethics.

JNMC was the **first medical college** in India to host research exchanges with MSAI. In the past two years, we have hosted **22 international medical students from 9 countries**. The students have participated in research projects in departments like **Cardiology, Microbiology, Community Medicine, Physiology and Biochemistry.** We have plans to host a greater number of students in the coming months.

Professional Exchanges

A **four weeks long clerkship/observership** in a clinical or pre-clinical field of medicine where the student has a chance to observe a different health care system and learn from foreign tutors. The aim is to promote cultural understanding and co-operation amongst medical students worldwide. The students can also learn and gain important soft and hard skills vital to being a health professional in the 21st century.

After the tremendous support received for Research Exchanges, MSAI has been approved by JNMC to host professional exchanges. We are expecting to begin hosting students in the upcoming year in departments like **Obstetrics and Gynaecology, Paediatrics, Surgery, General Medicine, Community Medicine and others.**

Exchanges for Indian Students

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

As most of these exchanges are bilateral, we also send Indian medical students to other countries for a similar exchange experience. This year, we received **19 applications out of which 7 students have been selected** to go an exchange. This number has been steadily increasing every year and is expected to increase even further in the coming months. The selection is conducted based on a predetermined **Point Based System** that takes into consideration many things ranging from academics, language proficiency, extra-curricular activities, work done for MSAI and so on. Once selected, these students are given a **Pre Departure Training** that helps them gain the best out of their exchanges while having a truly memorable experience.

Academic Quality & Capacity Building

We take a number of measures in order to ensure that these exchanges are truly beneficial to the exchange students. These steps ensure the academic quality of the exchange and make the month long trip for the students not just memorable but worthwhile. To ensure an educational experience of the highest quality, the professors at JNMC with the help of our local representatives carefully develop the projects. These projects are then reviewed and approved by an international team after which they become available for the exchange program.

We regularly conduct **Upon Arrival Trainings** for the incoming students to introduce them to the local culture and orient them for their upcoming exchange programs. The most recent ones were conducted in **July and August 2018** for **15 students from 5 countries.** We have also recently conducted a **Research Orientation and Open Access seminar** for the students. An **IFMSA certificate** is awarded upon successful completion of their exchange. The students are also given a **Handbook** to log their daily progress and discuss their expectations with their mentors.

To improve the exchange experience for all parties involved, we also conduct a number of capacity building activities across the country. We regularly conduct **Exchanges Workshops, which aim to educate students about exchanges,** and help MSAI motivate more members to partake in exchanges as participants as well as organizers.

Way forward

As we move closer to 2019, we are expecting to ramp up exchange activities. JNMC, with its stellar faculty and enthusiastic students, will play a central role in helping us achieve this. We are also looking to develop exchanges that concentrate on other areas of our work and believe that JNMC will be vital to our presence in not just Karnataka but also South India. It is an exciting time for our organization in the international as well as the national community and we it all to our partner institutes like JNMC.

MSAI

For any queries:
Karan Parikh
Vice President - Exchanges
98205 24326 | vpx@msaindia.org

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

1st December, 2017

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Kristic Antonia
DATE OF BIRTH: 26-12-1989
NATIONALITY: Austria
COUNTRY OF ORIGIN: Austria
PASSPORT NUMBER: U0285434

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Radiology
HOSPITAL: KLE's Dr. Prabhakar Kore Hospital
UNIVERSITY, CITY: India (MSAI) - Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/02/2018 at 28/02/2018

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

1st December, 2017

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Budnik Bitran Sigall
DATE OF BIRTH: 20-04-1993
NATIONALITY: Chile
COUNTRY OF ORIGIN: Chile
PASSPORT NUMBER: 183944010

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Internal Medicine-General
HOSPITAL: KLE's Dr. Prabhakar Kore Hospital
UNIVERSITY, CITY: India (MSAI) - Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/02/2018 at 28/02/2018

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

MSAI NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

1st December, 2017

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: abusada lues alejandro
DATE OF BIRTH: 30-07-1994
NATIONALITY: Chile
COUNTRY OF ORIGIN: Chile
PASSPORT NUMBER: F19524028

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Dermatology
HOSPITAL: KLE's Dr. Prabhakar Kore Hospital
UNIVERSITY, CITY: India (MSAI) - Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/02/2018 at 28/02/2018

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

msai india exchanges MSAI NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

17th May, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Bílek Martin
DATE OF BIRTH: 14-08-1996
NATIONALITY: Czech Republic
COUNTRY OF ORIGIN: Czech Republic
PASSPORT NUMBER: 41834388

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Radiology
HOSPITAL: Accepted in hospital named KLE's Prabhakar Kore charitable hospital.
UNIVERSITY, CITY: India (MSAI) - KLE, Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/07/2019 at 26/07/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

29th May, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Bikas Luca
DATE OF BIRTH: 27-02-1995
NATIONALITY: Hungary
COUNTRY OF ORIGIN: Hungary
PASSPORT NUMBER: BJ0356143

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Internal Medicine-General
HOSPITAL: Accepted in hospital named KLE's Prabhakar Kore charitable hospital.
UNIVERSITY, CITY: India (MSAI) - KLE, Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/08/2019 at 31/08/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

msai india exchanges MSAI NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

29th May, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Rusche Daniel
DATE OF BIRTH: 04-10-1994
NATIONALITY: Germany
COUNTRY OF ORIGIN: Germany
PASSPORT NUMBER: CG6PJ42MR

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Surgery-General
HOSPITAL: Accepted in hospital named KLE's Prabhakar Kore charitable hospital.
UNIVERSITY, CITY: India (MSAI) - KLE, Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/08/2019 at 31/08/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

MSAI NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

29th May, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Grabowiecka Roksana
DATE OF BIRTH: 04-04-1995
NATIONALITY: Poland
COUNTRY OF ORIGIN: Poland
PASSPORT NUMBER: EM 6685692

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Surgery-General
HOSPITAL: Accepted in hospital named KLE's Prabhakar Kore charitable hospital.
UNIVERSITY, CITY: India (MSAI) - KLE, Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/08/2019 at 28/08/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

MSAI NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

2nd May, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Lopez Luis
DATE OF BIRTH: 27-02-1994
NATIONALITY: Colombia
COUNTRY OF ORIGIN: Colombia
PASSPORT NUMBER: AQ234097

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Surgery-General
HOSPITAL: Accepted in hospital named KLE's Prabhakar Kore charitable hospital.
UNIVERSITY, CITY: India (MSAI) - KLE, Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 22/07/2019 at 18/08/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

msai india exchanges MSAI NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

4th July, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Savchyna Mariia
DATE OF BIRTH: 03-08-1997
NATIONALITY: Ukraine
COUNTRY OF ORIGIN: Ukraine
PASSPORT NUMBER: FL513998

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Neurology
HOSPITAL: KLEs Prabhakar Kore hospital
UNIVERSITY, CITY: India (MSAI) - KLE, Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/09/2019 at 30/09/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

Yours sincerely,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

4th July, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Kovac Mirna
DATE OF BIRTH: 23-10-1994
NATIONALITY: Croatia
COUNTRY OF ORIGIN: Croatia
PASSPORT NUMBER: 070637659

Our organization, which is a member of International Federation of Medical Students' Associations(IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Ophthalmology
HOSPITAL: KLEs Prabhakar Kore Hospital
UNIVERSITY, CITY: India (MSAI) - KLE, Belgaum, Karnataka
HOST COUNTRY: India
HOST ORGANISATION: MSAI India
PERIOD: 01/09/2019 at 30/09/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:

NATIONAL EXCHANGE OFFICER: Taher Tinwala
TEL: +919902327692
EMAIL: scope@msaindia.org

Stamp and signature of the NEO

msai india exchange MSAI NEO

Yours sincerely,

ATTESTED

Prof Dr V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA

International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship or medical training arranged by the

Standing Committee on Professional Exchange
International Federation of Medical Students' Associations

07 July 2018

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: Das Mahapat
DATE OF BIRTH: 23-03-1995
NATIONALITY: India
COUNTRY OF ORIGIN: India
PASSPORT NUMBER: M1761504

Our organization, which is a member of International Federation of Medical Students' Associations (IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will during the mentioned period, provide an board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Gynaecology/Obstetrics
HOSPITAL: Hospital Universitario de Vassouras
UNIVERSITY, CITY: Brazil (DENEM) - Vassouras/RJ UFS
HOST COUNTRY: Brazil
HOST ORGANISATION: DENEM
PERIOD: 01/09/2018 at 30/09/2018

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer.

NATIONAL EXCHANGE OFFICER: Douglas Ramon Lautert
TEL: +554[illegible]71435
EMAIL: neo.in.brazil@ifmsa.gmail.com

Name and signature of the NEO

[redacted]

Yours sincerely,

medical students

Standing Committee On Professional Exchange

Medical Students Association of India

Official Selection Letter

MSAI/SCOPE/2018/0144

29th November, 2018

To whomsoever it may concern,

This is to confirm that the following student is selected to participate in our bilateral medical student exchange program:

NAME OF STUDENT:	**UMA GUPTA**
SEX:	**FEMALE**
NATIONALITY:	**INDIAN**

Medical Students Association of India (MSAI) in collaboration with our counterpart organization of the host country, will arrange for a medical clerkship at one of the universities or affiliated hospitals for four weeks for the student. They will be provided accommodation and at least one meal per day at no extra cost. They will be placed under the supervision of a chief doctor at the department and will not receive any salary. The student is expected to resume their undergraduate medical studies after returning from the stated period of clerkship.

HOST COUNTRY:	**MEXICO**
HOST ORGANISATION:	**AMMEF**
PERIOD:	**JUNE 2019**

Medical student association of India (MSAI) is a non-government organization run for and by Indian medical students, who provide their services on a voluntary basis. It was founded in October 2011. MSAI-India is a registered society dedicated to work for medical students' welfare across the country. MSAI is also the National Member Organization (NMO) of the International Federation of Medical Students Association (IFMSA), which is the world's largest student organization representing more than 1.3 million medical students worldwide. It is also a non-government organization which is the main organization making this exchange possible with the help of its Standing Committee On Professional Exchanges (SCOPE).

We urge all authorities to be co-operative and helpful in order for this medical student to acquire a visa for the arranged clerkship and within a reasonable time.

I remain available for any clarification or further information regarding the student's clerkship. Confident in your understanding, I send my best regards and gratitude in advance.

Yours sincerely,

AATMIKA NAIR
National Exchange Officer - Outgoings
Standing Committee On Professional Exchange (SCOPE)
Medical Students Association Of India
Phone: +91-9820524326 | Email: scope@msaindia.org | Website: www.msaindia.org
Address: Suite S-473, Basement, Greater Kailash, Part-I, New Delhi

ATTESTED

Prof. Dr. V. A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a clerkship in medical training arranged by the
Standing Committee on Professional Exchange,
International Federation of Medical Students' Associations

15th September, 2019

To whom it may concern,

This is to confirm that the following student is accepted to participate in our bilateral exchange program for medical students:

NAME OF STUDENT: TIWARI SANSKRITI
DATE OF BIRTH: 10-03-1997
NATIONALITY: Indian
COUNTRY OF ORIGIN: India
PASSPORT NUMBER: P3870591

Our organization, which is a member of International Federation of Medical Students' Associations (IFMSA), will arrange a clerkship at one of our universities or affiliated university hospitals. We will, during the mentioned period, provide full board and lodging at no charge. The student will be placed under supervision of the administrating chief doctor at the department and will not get any salary.

DEPARTMENT: Surgery-General
HOSPITAL: Tanta University
UNIVERSITY, CITY: Egypt (IFMSA - Egypt) - Tanta -Tanta University
HOST COUNTRY: Egypt
HOST ORGANISATION: IFMSA - Egypt
PERIOD: 01/11/2019 - 30/11/2019

We urge all authorities to be helpful in order for the medical student to acquire a visa for the arranged Clerkship.

Any further questions regarding the mentioned student's clerkship should be directed to the National Exchange Officer:
NATIONAL EXCHANGE OFFICER: Khaled Azab
TEL: +201222777320
EMAIL: neo@ifmsa-eg.org

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a medical research training arranged by the
Standing Committee on Research Exchange,
International Federation of Medical Students' Associations

8th September, 2019

To whom it may concern,

Hereby **FASMR**, the National Member Organization of the International Federation of Medical Students' Associations officially invites the student mentioned below to participate in the research exchange program in the period:

from *01/11/2019 at 30/11/2019*

NAME OF STUDENT: Polana Srujana
DATE OF BIRTH: 18-05-1998
GENDER: Female
NATIONALITY: United States
COUNTRY OF ORIGIN: India
PASSPORT NUMBER: 565413424

The professional part of the program will be organized at the following university clinic/institute. The student will perform a clinical or scientific research project under the supervision of his tutor – one of the staff members. The student will not receive a salary during the period of his exchange period.

PROJECT: (Targu Mures) Hyperpolarization-activated inward current (If) blockade – a new approach to lone atrial fibrillat
HOSPITAL: University of Medicine, Pharmacy, Science and Technology of Targu Mures
UNIVERSITY, CITY: Romania (FASMR) - University of Medicine and Pharmacy Targu-Mures, Targu-Mures
HOST COUNTRY: Romania
HOST ORGANISATION: FASMR

The hosting organization will provide the student with lodging and boarding for the full period of his exchange period.

Any further information regarding the research exchange program can be obtained from the National Officer on Research Exchange:

NAME: Florentina-Cristina Scarlat
ADDRESS: str. Livezeni 12F, Targu Mures, Romania
TEL: +40729085092
EMAIL: nore.fasmr@gmail.com
Yours sincerely,

Florentina-Cristina Scarlat

Stamp and signature of the NORE

FEDERATIA ASOCIATIILOR STUDENTILOR IN MEDICINA DIN ROMANIA
NATIONAL RESEARCH EXCHANGE OFFICE

medical students worldwide

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

SCOPE
Professional Exchange

IFMSA
International Federation of Medical Students' Associations

CERTIFICATE

This is to certify that the Medical Student

SRUJANA POLANA
(full name, student ID)

From

INDIA
(country)

has successfully completed his/her professional exchange program.

The student worked in the department of PLASTIC SURGERY (department)

in SCTJU TARGU MURES, ROMANIA (hospital, city, country)

from 17th Nov 2019 (start date) to 6th Dec 2019 (end date) with _____ (number of days absent) days of absence

under the supervision of DR. ADRIAN BOTAN (name of tutor).

The student has fulfilled the requirements for a professional exchange according to the regulations of the Standing Committee on Professional Exchange of the International Federation of Medical Students Associations (IFMSA). The IFMSA Exchange programs are endorsed by the World Federation for Medical Education, who agrees that they are very professionally organised, with good academic outcomes.

Tutor's Signature Institution/department stamp	Hosting National/Local Exchange Officer	Sending National/Local Exchange Officer
SPITALUL CLINIC JUDETEAN MURES COMPARTIMENT CHIRURGIE PLASTICĂ MICROCHIRURGIE REGENERATIVĂ	LIGA STUDENȚILOR ROMÂNIEI TG. MUREȘ CIF 12291800	

ATTESTED

Prof. Dr. V.A KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA International Federation of Medical Students' Associations

SCORE Research Exchange

Certificate

This is to certify that the medical student

Patricia Capdevila Gaudens

full name

from **Catalonia**

country

has successfully completed their research exchange project

Identification, antibiotic susceptibility and analysis of virulence genes from dental plaque bacteria

name of research exchange project

at the **Basic Science Research Laboratory, KLE University**

name of department and university hospital

India during the period

country

1st July to 31st July under the supervision of

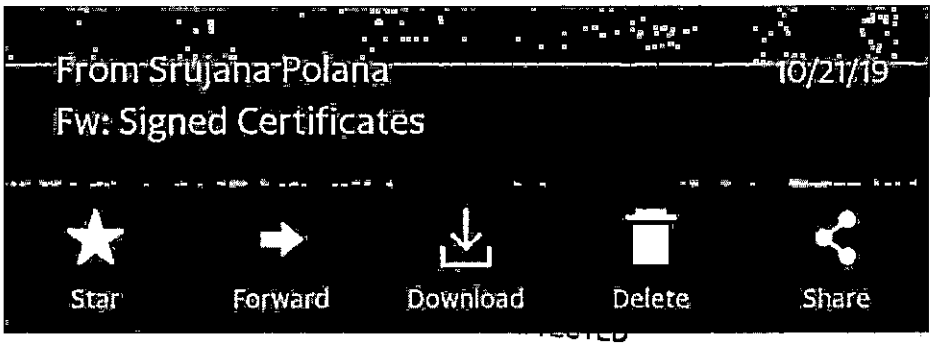
period

Dr. Suneel Dodamani.

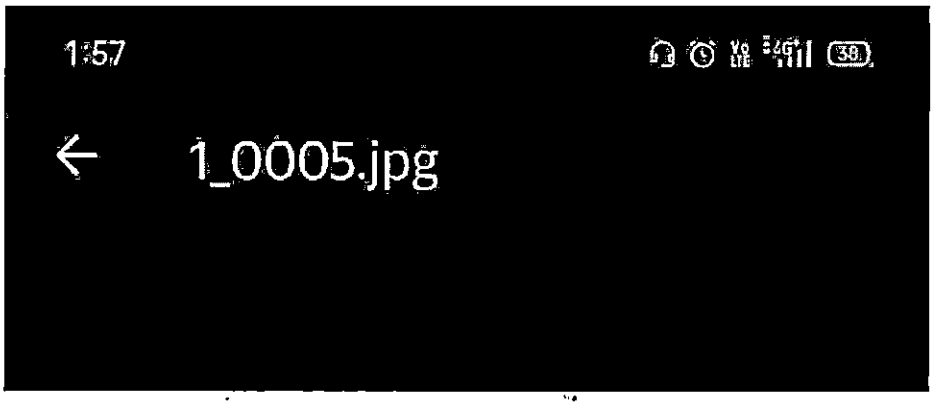
name of supervisor

The student has fulfilled the requirements for a research exchange according to the regulations of the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students Associations (IFMSA).

Tutor/Institution | Hosting NORE/LORE | Sending NORE/LORE



Prof Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI



IFMSA International Federation of Medical Students' Associations

SCORE Research Exchange

Certificate

This is to certify that the medical student

Lorenzo Pierangelo Treccani

full name

from **Italy**

country

has successfully completed their research exchange project

Effect of platelet rich plasma on gingival fibroblast adhesion and proliferation on titanium implant surfaces - In Vitro Study

name of research exchange project

at the **Basic Science Laboratory, KLE University**,

name of department and university/hospital

India during the period

country

1st July TO 31st July under the supervision of

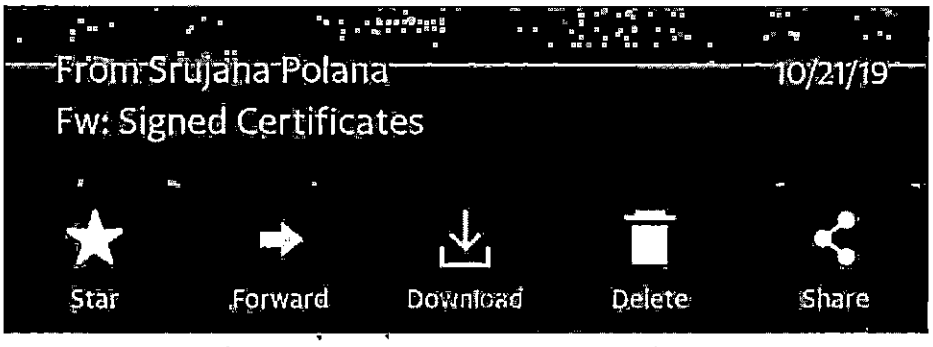
period

Ms. Dhanashree Patil,

name of supervisor

The student has fulfilled the requirements for a research exchange according to the regulations of the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students Associations (IFMSA).

Tutor/Institution | Hosting NORE/LORE | Sending NORE/LORE



Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Avinash Kavi

full name

has accomplished the task of Tutor for the medical student

Christan Andra

full name

supervising his/her work on the research project

Comprehensive review of Indian Primary Healthcare System

name of research project

at the department of **Community Medicine**

department

at **KLE University, Belagavi, India** during the period of

name of university and country

August 1, 2017 - August 30, 2017

period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future.

The **Medical Students' Association of India (MSAI-India)**

National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

NMO President
Anmol Patted

ATTESTED

Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

National Officer on Research Exchange
Dr. Bharat Sharma

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Sulakshana Baliga
full name

has accomplished the task of Tutor for the medical student

Katherine Bernard
full name

supervising his/her work on the research project

Risk Status Assessment in Pregnant Women in Rural Areas of Belagavi, India
name of research project

at the department of Department of Community Medicine
department

at Jawaharlal Nehru Medical College, Belagavi during the period of
name of university and country

July 2018
period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both cuturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future

The MSAI India
National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

ATTESTED

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that the medical student

ISABELLA ADORNO

full name

from BRAZIL

country

has successfully completed their research exchange project

ESTIMATION OF PREVALENCE OF METABOLIC SYNDROME AMONG FIRST YEAR MEDICAL STUDENTS

name of research exchange project

at the PHYSIOLOGY, KLE UNIVERSITY (KAHER), J.N. MEDICAL COLLEGE,

name of department and university/hospital

BELAGAVI, INDIA during the period

country

JULY 2018 under the supervision of

period

DR. ANITA. TELI .

name of supervisor

The student has fulfilled the requirements for a researcl exchange according to the regulations of the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students Associations (IFMSA).

(Dr. Anita Teli)

Tutor/Institution

Hosting NORE/LORE

Sending NORE/LORE

Department of Physiology
No.
Date:
J.N. Medical College, Belagavi

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Anita Teli

full name

has accomplished the task of Tutor for the medical student

Isabella Adorno

full name

supervising his/her work on the research project

Prevalence of Metabolic Syndrome in Medical Students and Correlating It with Body Mass Index of the Students

name of research project

at the department of Department of Physiology

department

at Jawaharlal Nehru Medical College, Belagavi during the period of

name of university and country

July 2018

period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future.

The IMSA India

National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

NMO President

ATTESTED

National Officer on Research Exchange

V.A.ROTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Girija J. Mahantshetti

full name

has accomplished the task of Tutor for the medical student

Cristina Fernandez Zavala

full name

supervising his/her work on the research project

Immunization Coverage of Under-5 Children in a Rural Area in Belagavi, India According to Universal Immunization Program

name of research project

at the department of Department of Community Medicine

department

at Jawaharlal Nehru Medical College, Belagavi during the period of

name of university and country

July 2018

period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future.

The MSAI India

National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

ATTESTED

LMO President

National Officer on Research Exchange

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Anuradha Patil
full name

has accomplished the task of Tutor for the medical student

Irene Morales Arjona
full name

supervising his/her work on the research project

Iodine Assessment In School Going Children and It's Relation of Iodine Deficiency and Cognitive Disability
name of research project

at the department of Department of Biochemistry
department

at Jawaharlal Nehru Medical College, Belagavi during the period of
name of university and country

July 2018
period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future

The MSAI India
National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

NMO President

ATTESTED

National Officer on Research Exchange

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that the medical student

FILIPPOS IOANNIS LAMPIS
full name

from GREECE
country

has successfully completed their research exchange project

ESTIMATION OF PREVALENCE OF METABOLIC SYNDROME AMONG FIRST YEAR MEDICAL STUDENTS
name of research exchange project

at the PHYSIOLOGY, KLE UNIVERSITY (KAHER) J.N. MEDICAL COLLEGE
name of department and university/hospital

BELAGAVI, INDIA during the period
country

JULY 2018 under the supervision of
period

DR. ANITA. TELI
name of supervisor

The student has fulfilled the requirements for a researcl exchange according to the regulations of the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students Associations (IFMSA).

(Dr. Anita. Teli)
Tutor/Institution

Hosting NORE/LORE

Sending NORE/LORE

Department of Physiology
No.
Date
J.N. Medical College

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Anita Teli

full name

has accomplished the task of Tutor for the medical student

Filippos Ioannis Lampis

full name

supervising his/her work on the research project

Prevalence of Metabolic Syndrome in Medical Students and Correlating it with Body Mass Index of the Students

name of research project

at the department of Department of Physiology

department

at Jawaharlal Nehru Medical College, Belagavi, during the period of

home university and country

July 2018

period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through out programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future.

The [illegible] MSAI India

National Member Organization

and the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

NMO President

ATTESTED

National Officer on Research Exchange

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Anuradha Patil
full name

has accomplished the task of Tutor for the medical student

Emma Bigas Alsina
full name

supervising his/her work on the research project

Iodine Assessment in School Going Children and it's Relation of Iodine Deficiency and Cognitive Disability
name of research project

at the department of Department of Biochemistry
department

at Jawaharlal Nehru Medical College, Belagavi during the period of
name of university and country

July 2018
period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future

The MSAI India
National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

NMO President

ATTESTED

National Officer on Research Exchange

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Sulakshana Baliga
full name

has accomplished the task of Tutor for the medical student

Bartlomiej Marcinkiewicz
full name

supervising his/her work on the research project

Risk Status Assessment in Pregnant Women in Rural Areas of Belagavi, India
name of research project

at the department of Department of Community Medicine
department

at Jawaharlal Nehru Medical College, Belagavi during the period of
name of university and country

August 2018
period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future.

The MSAI India
National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

ATTESTED

Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Sulakshana Baliga
full name

has accomplished the task of Tutor for the medical student

Magdalena Rybaczek
full name

supervising his/her work on the research project

Risk Status Assessment in Pregnant Women in Rural Areas of Belagavi, India
name of research project

at the department of Department of Community Medicine
department

at Jawaharlal Nehru Medical College, Belagavi during the period of
name of university and country

August 2018
period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future

The MSAI India
National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

ATE

...r Education
...AGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr. Girija J. Mahantshetti

full name

has accomplished the task of Tutor for the medical student

Silvia Nunez Laguna

full name

supervising his/her work on the research project

Evaluation of Immunization Coverage of Under-5 Children in a Rural Area in Belagavi, India According to Universal Immunization Program

name of research project

at the department of Department of Community Medicine

department

at Jawaharlal Nehru Medical College, Belagavi during the period of

name of university and country

August 2018

period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future.

Thea MSAI India

National Member Organization

and the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

NMO President

ATTESTED

National Officer on Research Exchange

Registrar
KLE Academy of Higher Education
and Research BELAGAVI

IFMSA
International Federation of Medical Student Associations

SCORE
Research Exchange

Certificate

This is to certify that

Dr Girija J. Mahantshetti

full name

has accomplished the task of Tutor for the medical student

Valery Gomez Merella Mohamed

full name

supervising his/her work on the research project

Evaluation of Immunization Coverage of Under-5 Children in a Rural Area in Belagavi, India According to Universal Immunization Program

name of research project

at the department of Department of Community Medicine

department

at Jawaharlal Nehru Medical College, Belagavi during the period of

faculty or university

August 2018

period

It is the mission of the Standing Committee On Research Exchange (SCORE) to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers to help shaping the world of science in the upcoming future.

The MSAI India

National Member Organization

and the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

NMO President

ATTESTED

National Officer on Research Exchange

Medical Students Association India

Reference Number: MSAI///EB//EX/2020/007 08th Oct 2020

To,
The Dean,
Jawaharalal Nehru Medical College,
Belagavi,Karnataka

Subject: Acknowledgement of Tutorship for Research Exchanges

Respected Madam/Sir,

This is to acknowledge that Dr. Nirmala Anand and Dr. Harpreet Kour have successfully hosted three Research Exchange Incoming students named Selma Heining, Nadia Rhizkisabrina and Valery Gomez from Indonesia, Germany and Catalonia respectively in the term 2018-19.

We congratulate Jawaharlal Nehru Medical College and K . L . E University on their successful endeavor. The Standing Committee on Research Exchange values the efforts and the interest that the professors of your esteemed medical college put to make the exchange period successful for our incoming exchange students.

We look forward to hosting more Research Exchange students with you for future IFMSA Research Exchanges.

Anindya Agarwal
Vice President for Exchanges
Medical Students Association of India
+91 9022733052 I vpx@msaindia.org

Jay Patel
National Officer on Research Exchange
Medical Students Association of India
+91 72030 30206 I score@msaindia.org

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

BIRTH PREPAREDNESS AND COMPLICATION READINESS IN PREGNANT WOMAN

Student:

Chaima Aichouch

4th Medical Student

Faculty of Medicine of Sfax,

Tunisia

Signature:

Guide:

Dr. Sulakshana S. Baliga

Associate professor

Dept. of community medicine

Jawarharlal Nehru Medical College

KAHER

Belgaum, Karnataka, India

Signature:

Dept. of Community Medicine J.N. Medical College Belagavi

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

BIRTH PREPAREDNESS AND COMPLICATION READINESS IN PREGNANT WOMAN

Student:

Francisco J. Pallares

6th semester

Faculty of Medicine – UACH

Chihuahua, Mexico

Signature:

Guide:

Dr. SulakshanaS. Baliga

Associate professor

Dept. of community medicine

Jawarharlal Nehru Medical College

KAHER

Belgaum, Karnataka, India

Signature:

Dept. of Community Medicine J.N. Medical College Belagavi

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

[redacted]

This is to certify that
Dr. Anita Teli
full name

Has accomplished the task of Tutor for the medical student
Alba Andrés Roca
full name

Supervising his/her work on the research project
Estimation of Prevalence of Hyperhomocysteinemia in healthy medical students of JN Medical College, Belagavi
name of research project

At the department of Physiology
Department

At Jawaharlal Nehru Medical College during the period of
Name of university and country

August 2019
Period

The mission of the Standing Committee On Research Exchange (SCORE) is to offer future physicians an opportunity to experience research and diversity in countries all over the world. This is achieved by providing a network of locally and internationally active students that globally facilitate access to research exchange projects. Through our programming and opportunities, we aim to develop both culturally sensitive students and skilled researchers intent on shaping the world of science in the upcoming future

The MSAI, India
National Member Organization

and the Standing Committee On Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA) recognize the aforementioned tutor's contribution to our organization and to a worldwide development of research exchange.

ATTESTED

NMO President

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

National Officer On Research Exchange

Certificate

This is to certify that the student

PEGAH KOSHSALIGHEH
full name

from TURKEY
country

has succesfully completed their research exchange

ESTIMATION OF PREVALENCE OF HYPERHOMOCYSTINEINEMIA IN HEALTHY MEDICAL STUDENTS
name of the research exchange project

at the PHYSIOLOGY, JAWAHARLAL NEHRU MEDICAL COLLEGE,
name of department and university/hospital

INDIA during the period
country

1ST AUGUST 2019 - 31ST AUGUST 2019 under the supervision of
period

DR. ANITA TEU
name of supervisor

he student has fulfilled the requirements for a research exchange according
o the regulations of the Standing Committee on Research Exchange (SCORE
f the International Federation of Medical Students' Associations (IFMSA).

Tutor/Institution Hosting NORE/LORE Sending NORE/LORE

Department of Physiology

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a medical research training arranged by the
Standing Committee on Research Exchange,
International Federation of Medical Students' Associations

1st March, 2018

To whom it may concern,

Hereby **IFMSA-Brazil**, the National Member Organization of the International Federation of Medical Students' Associations officially invites the student mentioned below to participate in the research exchange program in the period:

from *01/05/2018 at 29/05/2018*

NAME OF STUDENT: Magadum Harshita
DATE OF BIRTH: 19-01-1998
GENDER: Female
NATIONALITY: India
COUNTRY OF ORIGIN: India
PASSPORT NUMBER: M2330424

The professional part of the program will be organized at the following university clinic/institute. The student will perform a clinical or scientific research project under the supervision of his tutor – one of the staff members. The student will not receive a salary during the period of his exchange period.

PROJECT: Identification of Snake venom-derived therapeutic proteins from Bothropsjararaca for cancer treatment.
HOSPITAL: hospital pio xii
UNIVERSITY, CITY: Brazil (IFMSA-Brazil) - Faculdade de Ciencias da Saude de Barretos Dr. Paulo Prata, Barretos
HOST COUNTRY: Brazil
HOST ORGANISATION: IFMSA-Brazil

The hosting organization will provide the student with lodging and boarding for the full period of his exchange period.

Any further information regarding the research exchange program can be obtained from the National Officer on Research Exchange:

NAME: Tulio Maia
ADDRESS: Rua Henrique Dias, 496 - Casa do estudante. Recife-PE . zip code: 52010100
TEL: + 55 81997231707
EMAIL: nore@ifmsabrazil.org
Yours sincerely,

Tulio Maia

Stamp and signature of the NORE

IFMSA Brazil | NORE
International Federation of Medical Students' Associations
ifmsabrazil.org | CNPJ 00233001 56/0001-13
Tulio Henrique Maia de Almeida Oliveira

medical students worldwide

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a medical research training arranged by the
Standing Committee on Research Exchange,
International Federation of Medical Students' Associations

27th May, 2018

To whom it may concern,

Hereby **IFMSA-Spain**, the National Member Organization of the International Federation of Medical Students' Associations officially invites the student mentioned below to participate in the research exchange program in the period:

from *01/06/2018 at 30/06/2018*

NAME OF STUDENT: Polana Srujana
DATE OF BIRTH: 18-05-1998
GENDER: Female
NATIONALITY: United States
COUNTRY OF ORIGIN: India
PASSPORT NUMBER: 565413424

The professional part of the program will be organized at the following university clinic/institute. The student will perform a clinical or scientific research project under the supervision of his tutor – one of the staff members. The student will not receive a salary during the period of his exchange period.

PROJECT: Role of apolipoprotein D in the demyelination and remyelination processes: implications in multiple sclerosis
HOSPITAL: Hospital Universitario Central de Asturias (HUCA)
UNIVERSITY, CITY: Spain (IFMSA-SPAIN) - University of Oviedo, Oviedo
HOST COUNTRY: Spain
HOST ORGANISATION: IFMSA-Spain

The hosting organization will provide the student with lodging and boarding for the full period of his exchange period.

Any further information regarding the research exchange program can be obtained from the National Officer on Research Exchange:

NAME: Maria Gonzalez Bisquert
ADDRESS: Edificio de ciencias de salud, Av. Ramón y Cajal, 7, 47005 Valladolid
TEL: +34 690299794
EMAIL: ifmsa.nore.spain@gmail.com
Yours sincerely,

Maria Gonzalez Bisquert

Stamp and signature of the NORE

Prof. Dr. V.A.KOTHIVALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that the Medical Student

Srujana Polana

full name

from India

country

has successfully completed his/her research exchange project entitled

Cuantificación electrocardiográfica de la respuesta a la infusión de Ajmalina en el diagnóstico del Sd. de Brugada

name of the research exchange project

in the department of Cardiology,

department

at HUCA, Spain during the period

name of the university and country

June 2018 under the supervision

period

of David Calvo Cuervo.

the name of the doctor

The student has fulfilled the requirements for a research exchange according to the regulations of the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students´Associations (IFMSA).

Tutor/Institution

National/ Local Officer on Research Exchange

IFMSA-Spain
N. O. R. E.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Journal of
Clinical Medicine

MDPI

Article

Spectral Analysis of the QT Interval Increases the Prediction Accuracy of Clinical Variables in Brugada Syndrome

Daniel García-Iglesias [1,2], Francisco Javier de Cos [3], Francisco Javier Romero [4], Srujana Polana [5], José Manuel Rubín [1,2], Diego Pérez [1,2], Julián Reguero [1,2], Jesús María de la Hera [1,2], Pablo Avanzas [1,2], Juan Gómez [2,6], Eliecer Coto [2,6], César Morís [1,2] and David Calvo [1,2,3,7,*]

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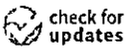

Abstract: (1) Background: The clinical management of Brugada Syndrome (BrS) remains suboptimal. (2) Objective: To explore the role of standard electrocardiogram (ECG) spectral analysis in diagnosis and risk stratification. (3) Methods: We analyzed 337 patients—43 with a spontaneous type I ECG pattern (Spont-BrS), 112 drug induced (Induct-BrS), and 182 with a negative response to the drug challenge (negative responders (NR)). ECGs were processed using the wavelet transform (high frequency: 85 to 130 Hz). (4) Results: The power of the high-frequency content in the ST segment (Total ST Power; $nV^2Hz^{-1}10^3$) was higher in BrS compared with NR patients (Spont-BrS: 28.126 (7.274–48.978) vs. Induc-BrS: 26.635 (15.846–37.424) vs. NR: 11.13 (8.917–13.343); $p = 0.002$). No differences were observed between ECG patterns in BrS patients. However, the Total ST Power of the type II or III ECG in NR patients was lower than in the same ECG patterns recorded from BrS patients (BrS: 31.07 (16.856–45.283); vs. NR: 10.8 (7.248–14.352) $nV^2Hz^{-1}10^3$; $p = 0.007$). The Total ST Power, age, and family history of BrS were independent predictors of positive responses to drug testing. Comparing models with versus those without Total ST Power, the area under the received operator curve (ROC) curve increased (with 0.607 vs. without 0.528, $p = 0.001$). Only syncope was associated with an increased risk (follow-up 55.8 ± 39.35 months). However, the area under the ROC curve increased significantly when the Total ST Power was included as a covariate (with 0.784 vs. without 0.715, $p = 0.04$). (5) Conclusions: The analysis of the high-frequency content of ECG signals increases the predictive capability of clinical variables in BrS patients.

Keywords: Brugada syndrome; spectral analysis; diagnosis; sudden cardiac death; prognosis

1. Introduction

Brugada syndrome (BrS) is an inherited disease with an increased risk of Sudden Cardiac Death (SCD) in apparently healthy individuals [1]. The diagnosis relies on the demonstration of a type I electrocardiogram (ECG) pattern, either occurring spontaneously or induced by the infusion of sodium channel blockers. However, the latter is questioned because of the suboptimal sensitivity of drug testing, which may negatively affect the prognosis in patients with false-negative responses [2]. Similarly, the intermittence of ECG patterns introduces a challenge to risk stratification and explains the conflicting results along different studies [3]. In fact, a significant portion of patients are reclassified with time and with an increasing number of ECG explorations [2].

Those limitations inherent to the visual inspection of ECG tracings might be overcome by quantitative analysis of the ECG signals. For that purpose, we previously demonstrated that the spectral decomposition of ECG signals with the wavelet transform of the QRS complexes allows for appropriate characterization of the high-frequency content, which exert a differential behavior between healthy individuals and patients affected by severe cardiac arrhythmias leading to SCD [4]. In the present work, we analyze an extensive cohort of patients with BrS and provide evidence of the potential utility of the spectral decomposition of ECG signals in improving the performance of diagnostic maneuvers and the accuracy of risk assessment beyond other variables commonly used in the clinic.

2. Methods

2.1. Population and Recording Protocol

From April 2005 to July 2018, data were collected from 337 patients with suspicious or confirmed BrS who were referred to our arrhythmia unit for diagnostic or therapeutic purposes (Figure S1). Patients were managed according to accepted recommendations at the time of evaluation [5] and classified as spontaneous BrS patients (Spont-BrS; patients displaying a spontaneous type I ECG pattern at the time of diagnosis), drug-induced BrS patients (Induc-BrS; patients displaying a type I ECG pattern during provocative testing with sodium blockers) and negative responder patients (NR; patients with suspicious BrS and a negative response to the provocative testing with sodium blockers).

Clinical baseline variables were obtained at the outpatient clinic. Patients displaying a spontaneous type I ECG were confirmed as having BrS, underwent risk stratification, and were referred for standard digital 12-lead ECG acquisition (see below). Patients with suspected BrS were referred for provocative testing with sodium blockers. According to recommendations, intravenous flecainide was continuously infused at a rate of 2.0 mg/kg body weight over 10 min (maximum dosage, 150 mg) [6]. Ajmaline was continuously infused at a rate of 1 mg/kg body weight over 10 min (maximum dosage, 50 mg). Before drug infusion, we checked for the absence of a type I ECG, both at the standard precordial position (V1 and V2 at the fourth intercostal space) and the high precordial position (V1 and V2 at the second intercostal space). At the end of the provocative testing, we explored the high precordial position for better sensitivity. ECG tracings were analyzed by two independent cardiac electrophysiologists and classified by consensus according to published recommendations as type I, II, or III [5]. The provocative testing was considered to display a positive response if the patient exhibited a type I ECG at any time during the protocol. The patients were retrospectively reviewed, and this study protocol was approved by the Ethics Committee. All patients gave informed consent.

2.2. Signal Processing

Standard ECGs (12 leads) were digitally used to extract the QT complexes (see Supplementary Materials for details) [4]. The time–frequency data of each QT complex were collected using the Wavelet transform (see Supplementary Materials for details). In accordance with previous reports, high-frequency content was defined as being within the range of 85 to 130 Hz [4]. Calculations were performed with R software (http://www.r-project.org) [7].

To analyze the distribution of the high-frequency content, we computed the cumulative power contained at each time epoch of the QT interval (Figure 1). From the obtained distribution, we defined (i) the Peak Power as the highest cumulative power of the high-frequency content, (ii) the Total Power as the area under the curve of the whole power function, (iii) the Total QRS Power as the area under the curve of the power function along the QRS interval, (iv) the Total ST Power as the area under the curve of the power function along the ST–T wave interval, and (v) the QRS to ST Total Power ratio as the ratio between the Total QRS Power and Total ST-Power.

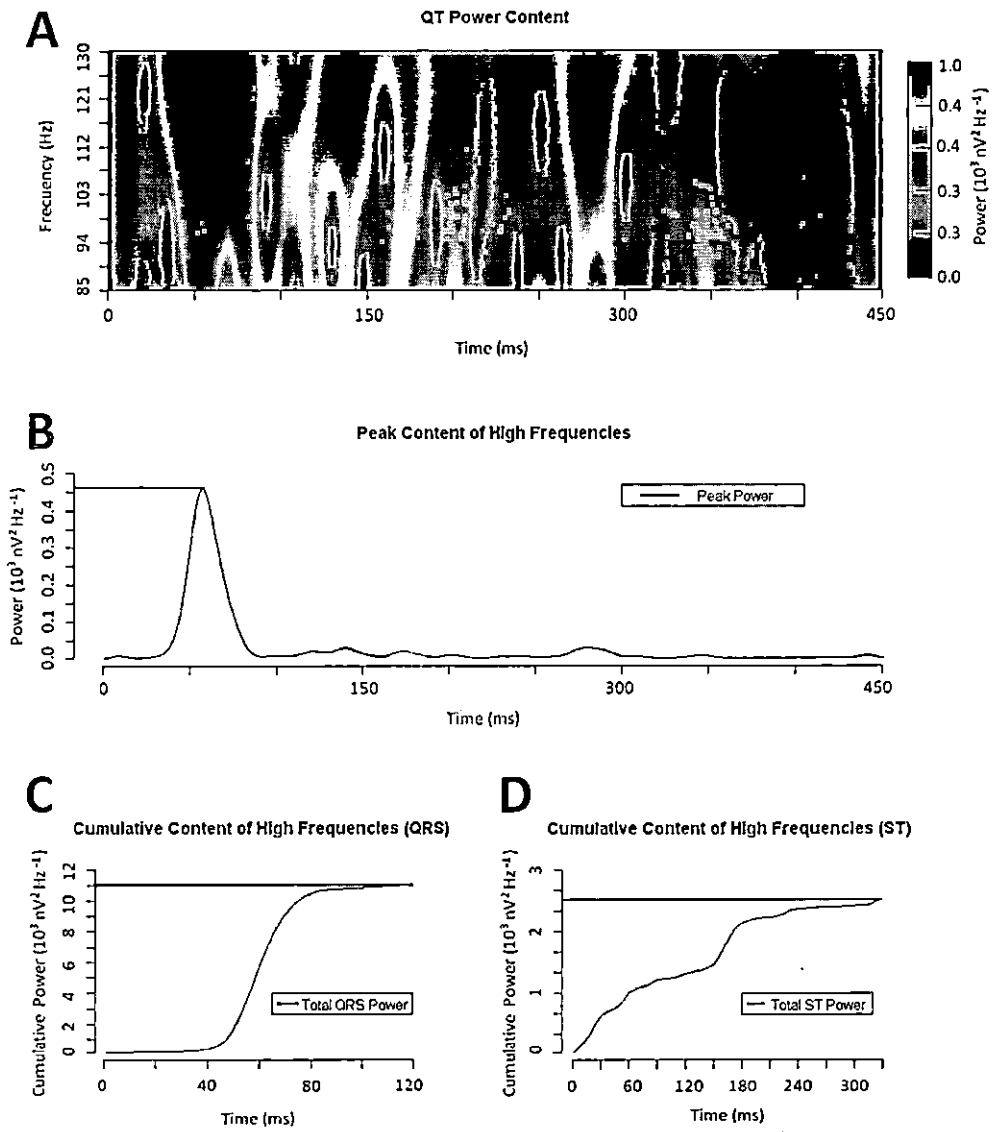

Figure 1. Example of a wavelet continuous transform on a QRS complex (frequency range: 85–130 Hz). **Panel A**: Power spectrum of the QRS complex. **Panel B**: Total high-frequency content at each time epoch. The brown dotted line marks the Peak Power. **Panel C & D**: Cumulative power of the high-frequency content along the QRS and ST interval. The colored dotted lines mark the Total QRS and ST Power respectively.

2.3. Definitions

The terms sudden cardiac arrest (SCA) and sudden cardiac death (SCD) have been defined previously in the literature [8]. Symptomatic patients were defined according to the presence of any type of syncope [2,9,10]. The end point of this study was the occurrence of SCA, SCD, or appropriate therapy using an implantable defibrillator (ICD) to treat life-threatening ventricular arrhythmias during the follow-up period.

2.4. Follow-Up

Spont-BrS and Induc-BrS patients had an annual follow-up at the outpatient clinic. Risk stratification was performed according to current clinical standard recommendations, taking patient preferences into consideration. An electrophysiological study was also performed according to the state-of-the-art methods at the time. The induction of sustained ventricular fibrillation was followed by preventive ICD implantation. Alternatively, an ICD was recommended for high-risk patients, including SCA survivors and symptomatic patients. In contrast, patients displaying a negative response were not stratified according to the BrS standards. Every patient was also directly interviewed in the outpatient clinic at the time of this study, and data regarding the clinical profile were re-checked if necessary.

2.5. Statistical Analysis

Categorical variables are reported as numbers and percentages. Continuous variables are reported as means (±standard deviation [SD] or 95% Confidence Intervals [CI95%]). The chi-square test and the Student t test (paired or unpaired as appropriate) were used for univariate analysis to contrast different variables. For multilevel univariate analysis, an ANOVA test was used. Logistic regression was used to contrast different variables as predictors of the responses to provocative testing and SCA/SCD/appropriate therapies from the ICD during follow-up. A received operator curve (ROC) was constructed in both cases to evaluate the diagnostic and prognostic accuracy of the multivariate analysis, comparing the different models with the deLong test. Analyses were performed using R software (http://www.r-project.org), and statistical significance was established at $p < 0.05$.

3. Results

3.1. Patients and Clinical Variables

The distribution of patients and clinical characteristics are summarized in Figure S1 and Table 1, respectively. Overall, BrS patients were slightly older than NR patients. Most of the Spont-BrS patients displayed a type I ECG pattern at the time of the digital ECG recording. Digital ECG records, acquired at the beginning of provocative testing, exhibited some differences between Induct-BrS and NR patients. Thus, most of the patients with a negative response to the provocative testing exhibited a normal ECG pattern at baseline, whereas the most frequent ECG pattern at baseline in the Induct-BrS cohort was the type II ECG pattern. The presence of syncope was equally distributed between groups. However, cardiac syncope and SCA were more frequent in BrS patients. An ICD was implanted in 22 Spont-BrS patients (51.16%) and in 23 Induct-BrS patients (20.54%), mainly because of sustained ventricular fibrillation induction in the electrophysiological study (11 patients; 24.44%) or previous cardiogenic syncope (13 patients; 28.89%)].

Table 1. Comparison of clinical variables between groups.

	Spont-BrS (N = 43)	Induc-BrS (N = 112)	NR Patients (N = 182)	*p* Value
Clinical features				
Age (years)	44.05 (12.3)	43.61 (14.51)	38.64 (14.98)	0.004
Male gender (%)	30 (90.7)	70 (62.5)	137 (75.28)	0.001
Family history of SCD at age <45 years (%)	18 (41.86)	68 (60.71)	73 (40.11)	0.002
Syncope (%)	11 (25.58)	28 (25)	56 (30.77)	0.521
Cardiac syncope (%)	7 (16.28)	12 (10.71)	5 (2.75)	0.002
SCA (%)	5 (11.63)	9 (8.04)	1 (0.549)	0.001
Smoker (%)	12 (27.9)	29 (25.89)	47 (25.82)	0.96
Hypertension (%)	7 (16.28)	18 (16.07)	21 (11.54)	0.473
Diabetes mellitus (%)	1 (2.33)	4 (3.57)	3 (1.65)	0.575
Dyslipidemia (%)	8 (18.61)	22 (19.64)	14 (7.69)	0.007
Cardiomyopathy (%) †	3 (6.98)	3 (2.68)	9 (4.95)	0.455
Cardiovascular drugs (%) ‡	11 (25.58)	18 (16.07)	23 (12.64)	0.104
PES Test performed	26 (60.47)	37 (33.04)	3 (1.65)	<0.001
Positive PES	8 (18.6)	4 (3.57)	0 (0)	<0.001
ICD implanted	22 (51.16)	23 (20.54)	2 (1.1)	<0.001
ECG pattern at the time of the digital record				
BrS type I (%)	38 (88.37)	0	0	<0.001
BrS type II (%)	3 (6.98)	59 (52.68)	36 (19.78)	<0.001
BrS type III (%)	0	22 (19.64)	39 (21.43)	0.004
BrS type II–III (%)	3 (6.98)	81 (72.62)	75 (41.21)	<0.001
Normal (%)	0	25 (22.32)	75 (41.21	<0.001

† All the cases displayed discrete left ventricle hypertrophy due to hypertension. ‡ All the cases on anti-hypertensive and/or lipid-lowering drugs. BrS: Brugada syndrome; SCA: sudden cardiac arrest; SCD: sudden cardiac death; Spont-BRS: spontaneous BrS patients; Induc-BRS: drug-induced BrS patients; NR: negative responder patients; PES: programmed electrical stimulation.

3.2. *The High-Frequency Content along the QT Interval*

The distribution of the high-frequency content along the QT interval was different between BrS patients and NR patients (Figure 2 and Table 2). Overall, the Total Power and the Total ST Power were significantly higher in BrS patients (either Spont-BrS or Induct-BrS) compared with NR patients. However, those differences were mainly determined by the differences observed in the right precordial leads (V1 and V2; See Table 2), while comparisons between other precordial leads displayed non-significant differences (V3 to V6; Total Power: Spont-BrS 27.932 (13.393–42.471) vs. Induc-BrS 42.991 (14.673–71.31) vs. NR patients 26.686 (22.626–30.747) $10^3 nV^2Hz^{-1}$, $p = 0.483$; Total ST Power: Spont-BrS 12.821 (2.356–23.286) vs. Induc-BrS 12.735 (7.447–18.023) vs. NR patients 7.815 (6.139–9.49) $10^3 nV^2Hz^{-1}$; $p = 0.062$).

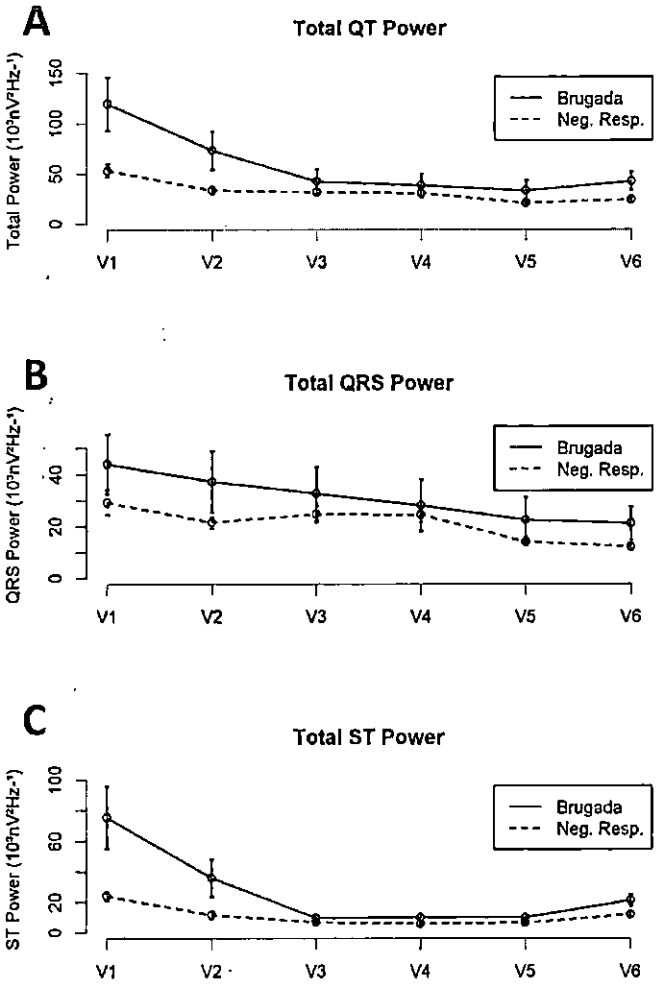

Figure 2. High-frequency content along precordial leads; Comparison between BrS patients and NR. **Panel A:** Total Power in the QT interval. **Panel B:** Total Power in the QRS interval. **Panel C:** Total Power in the ST interval.

Table 2. Comparative analysis of the high-frequency content between different clinical conditions.

	Spont-BrS	Induct-BrS	NR Patients	*p* Value
	All precordial leads			
Peak Power	0.734 (0.616–0.852)	1.439 (0.916–1.962)	0.871 (0.786–0.956)	0.677
Total Power	46.693 (34.811–58.575)	62.188 (46.143–78.233)	32.161 (29.752–34.57)	0.095
Total QRS Power	18.567 (15.884–21.25)	35.553 (22.559–48.547)	21.031 (19.119–22.943)	0.623
Total ST Power	28.126 (17.793–38.459)	26.635 (21.19–32.08)	11.13 (10.009–12.251)	0.002
QRS to ST Total Power	5.256 (3.947–6.565)	5.762 (4.931–6.593)	9.724 (8.075–11.373)	0.045
	Right precordial leads			
Peak Power	0.897 (0.74–1.054)	1.705 (1.127–2.283)	0.917 (0.801–1.033)	0.468

Table 2. *Cont.*

	Spont-BrS	Induct-BrS	NR Patients	*p* Value
Total Power	84.216 (52.704–115.728)	100.581 (77.381–123.781)	43.111 (38.832–47.39)	0.017
Total QRS Power	25.48 (21.46–29.5)	46.147 (30.805–61.489)	25.35 (22.267–28.433)	0.451
Total ST Power	58.736 (30.649–86.823)	54.434 (40.921–67.947)	17.761 (15.586–19.936)	0.003
QRS to ST Total Power	4.142 (3.075–5.209)	4.06 (3.445–4.675)	6.023 (5.067–6.979)	0.133

Figures within brackets denote the 95% confidence interval (CI95%). Units for Peak Power, Total Power, Total QRS Power, and Total ST Power are expressed as $10^3 nV^2 Hz^{-1}$.

When BrS patients were analyzed according to the time-domain description of the ECG records, we found no statistically significant differences between ECG patterns with regard to their high-frequency content (Table S1). However, we observed significant differences in the Total ST Power contained in type II or III ECG patterns (combined) when comparing NR with BrS patients (Table 3). Such differences were not found when we compared normal ECG patterns from BrS patients with those from NR patients (see Table S2 for detailed description). An independent analysis of type II and III ECG patterns is presented in Table S3. In summary, significant differences regarding the Total ST Power were identified when comparing Brugada patients and NR displaying a type II ECG pattern. Those differences were not observed when analyzing individuals displaying a type III ECG pattern. However, the number of patients available for analysis in that category was low, and therefore, the results were probably affected by a lack of statistical power.

Table 3. Comparative analysis of the high-frequency content between different electrocardiogram (ECG) patterns and clinical conditions.

	ECG Type I	ECG Type II or III		
	BrS Patients	**BrS Patients**	**NR Patients**	***p***
	All precordial leads			
Peak Power	0.629 (0.421–0.836)	1.518 (0.186–2.85)	1.07 (0.762–1.379)	0.517
Total Power	47.415 (20.269–74.561)	69.721 (28.191–111.251)	36.259 (27.264–45.253)	0.121
Total QRS Power	16.665 (11.358–21.972)	38.651 (5.058–72.244)	25.458 (18.461–32.455)	0.446
Total ST Power	30.75 (7.171–54.329)	31.07 (16.856–45.283)	10.8 (7.248–14.352)	0.007
QRS to ST Total Power	3.849 (2.131–5.566)	5.853 (3.926–7.779)	12.132 (6.002–18.262)	0.055
	Right precordial leads			
Peak Power	0.886 (0.529–1.244)	1.948 (0.43–3.466)	1.209 (0.771–1.647)	0.355
Total Power	89.832 (17.724–161.941)	120.243 (59.55–180.936)	51.683 (35.198–68.167)	0.033
Total QRS Power	25.041 (15.957–34.126)	53.695 (13.362–94.027)	32.757 (20.998–44.516)	0.324
Total ST Power	64.791 (0.574–129.008)	66.549 (31.128–101.969)	18.926 (11.609–26.242)	0.01
QRS to ST Total Power	3.471 (1.768–5.173)	4.284 (2.783–5.785)	7.666 (3.581–11.751)	0.125

Figures within brackets denote the CI95%. Units for Peak Power, Total Power, Total QRS Power, and Total ST Power are expressed as $10^3 nV^2 Hz^{-1}$.

3.3. Drug Challenge and the High-Frequency Content

Overall, 294 patients were admitted for drug challenge testing, and digitalized ECG records were obtained (baseline ECG records). We analyzed the diagnostic yield of the high-frequency content to predict positive responses to the test. In summary, 182 patients were classified as NR and 112 were classified as Induct-BrS. Univariate analysis demonstrated the Total Power and the Total ST Power at the right precordial leads, along with age, male gender, and family history of SCD or BrS, as variables with significant associations with the final drug testing results (Table 4). In the Multivariate Analysis, the Total ST Power, age, and family history of BrS were also found to be independent predictors of the final drug testing results (Table 4). Compared with a simplified model including age and family history of BrS, a completed model including the Total ST Power displayed an increased diagnostic yield. The inclusion of the Total ST Power significantly increased the ROC area under the curve compared with the simplified model (AUC completed model 0.607 vs. simplified model 0.528, $p = 0.001$; Figure 3A).

Table 4. Results of the Univariate and Multivariate analyses.

	Univariate		Multivariate	
	HR	*p*	HR	*p*
Model for prediction of positive response to the drug challenge				
Peak Power	3.251 (0.8–13.209)	0.099		
Total Power	1.054 (1.019–1.091)	0.003		
Total QRS Power	1.045 (0.991–1.102)	0.101		
Total ST Power	1.106 (1.043–1.174)	0.001	1.251 (1.082–1.447)	0.003
QRS to ST Total Power ratio	0.678 (0.407–1.13)	0.136		
Age	1.005 (1.002–1.009)	0.006	1.005 (1.001–1.008)	0.014
Male	0.865 (0.766–0.977)	0.02	0.925 (0.814–1.05)	0.225
Familiar History of SCD	1.215 (1.089–1.356)	0.001		
Familiar History of BrS	1.203 (1.066–1.358)	0.003	1.158 (1.019–1.317)	0.025
Syncope	0.936 (0.827–1.059)	0.289	0.914 (0.81–1.032)	0.146
Model for prediction of arrhythmic events during follow-up				
Peak Power	0.997 (0.414–2.398)	0.994		
Total Power	1.011 (0.991–1.031)	0.285		
Total QRS Power	0.999 (0.967–1.033)	0.967		
Total ST Power	1.025 (0.996–1.056)	0.096	1.041 (0.966–1.123)	0.291
QRS to ST Total Power ratio	0.536 (0.27–1.065)	0.075		
Age	1 (0.997–1.003)	0.905		
Spontaneous Type I Pattern	1.037 (0.936–1.148)	0.488	1.026 (0.923–1.141)	0.629
Male	1.036 (0.938–1.145)	0.482	1.041 (0.939–1.155)	0.441
Familiar History of SCD	0.955 (0.871–1.047)	0.322	0.951 (0.869–1.041)	0.278
Familiar History of BrS	0.928 (0.842–1.023)	0.133		
Syncope	1.206 (1.09–1.335)	<0.001	1.197 (1.079–1.329)	0.001
Positive PES	0.907 (0.765–1.075)	0.259	0.898 (0.756–1.067)	0.219
SCN5a Mutation	0.96 (0.86–1.073)	0.472	0.975 (0.873–1.089)	0.652

Numbers within brackets denote the CI95%.

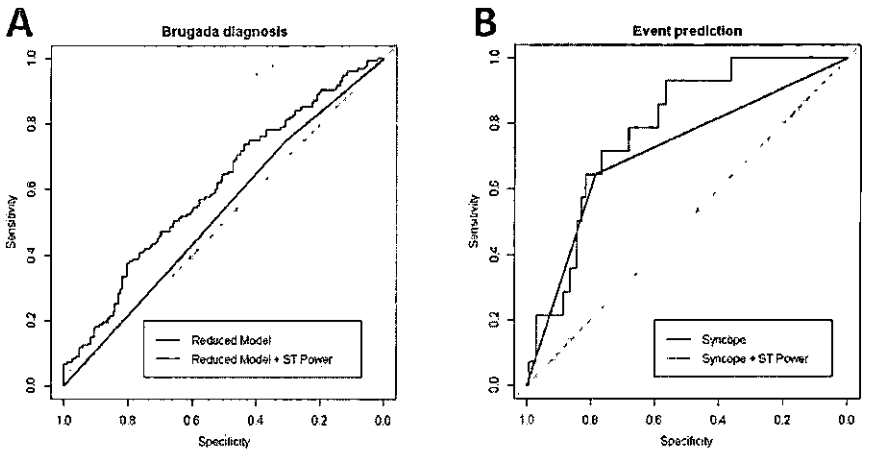

Figure 3. Comparative received operator curve (ROC) curve analysis from multivariate models. **Panel A**: ROC curve for BrS diagnosis during the drug testing. **Panel B**: ROC curve for arrhythmic event prediction.

In a subset of 211 patients, digitalized ECG data were also collected after Flecainide (n = 168) or Ajmaline (n = 43) infusion. In that cohort, 61 patients displayed a type I ECG pattern after drug testing and were subsequently classified as Induct-BrS patients. Overall, drug infusion attenuated the high-frequency content along the QT interval in all individuals (Figure 4 and Table S4). As displayed in Figure 4, no significant differences were observed in the rate of attenuation when comparing Induct-BrS patients with NR patients. In addition, Flecainide and Ajmaline attenuated the high-frequency content in a similar way (see Table S4 for details).

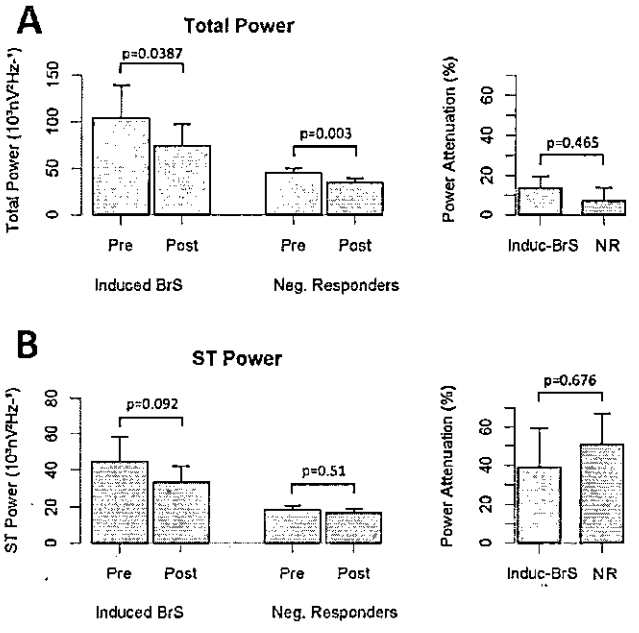

Figure 4. Effects of drug infusion on the high-frequency content of the QT interval for right precordial leads. **Panel A**: Total Power and attenuation of Total Power in Brugada patients and NR. **Panel B**: ST Power and attenuation of ST Power in Brugada patients and NR.

3.4. Prediction of Clinical Events During Follow-Up in Patients with Brugada Syndrome

The mean follow-up period was 55.8 ± 39.4 months (no patient was lost to follow-up). Overall, 14 patients (five Spont-BrS and nine Induct-BrS) had SCA or received appropriate ICD therapies because of ventricular fibrillation (9.03%). BrS patients with clinical events expressed a non-significant increase in the Total ST Power (51.18 [4.37–97.99] vs. 24.32 [14.86–33.79], $p = 0.248$) and in the Total ST Power along the right precordial leads (113.52 [−14.5 to 241.54] vs. 49.1 [25.17–73.04], $p = 0.307$). It translates into a significant reduction in the QRS to ST Total Power ratio compared with BrS patients without clinical events (Table S5). In the univariate and multivariate analyses, cardiac syncope was the unique variable associated with an increased risk of clinical events (Table 4). However, the inclusion of the Total ST Power contained in right precordial leads in addition to cardiac syncope resulted in the increased predictive capability of the model. As shown in Figure 3B, the completed model, including syncope and Total ST Power, increased the ROC area under the curve significantly compared with the model with syncope alone (completed model AUC 0.784 vs. only syncope model AUC 0.715, $p = 0.04$). Comparisons between BrS patients displayed that those with clinical events expressed a significant reduction in the QRS to ST Total Power ratio compared with asymptomatic BrS patients (Table S5).

4. Discussion

The results of our study show that the analysis of the high-frequency content of surface ECG signals adds diagnostic and prognostic information in BrS patients, as it helps to increase the predictive capability of clinical variables. We demonstrated that the high-frequency content exerts differential behaviors between BrS patients and controls, which is, to some extent, independent of the time domain classification of ECG patterns. Moreover, despite this differential behavior, the clinical significance shown in the ROC analysis for this parameter seems low compared with what was seen for the event prediction analysis. Because of that and although their role in BrS pathophysiology was not demonstrated in our work, the improvement in predictive capabilities adds more evidence in favor of the previously reported link between the high-frequency content and the risk for severe cardiac arrhythmias [4].

We are aware that translation to the clinic is far from being done; however, with the present work, we have paved the way for new quantitative measurements on ECG signals with the potential to improve the clinical management of BrS patients.

4.1. The Plausible Link between the High-Frequency Content and the Arrhythmogenic Substrate

Recent studies in BrS patients demonstrated that the arrhythmogenic substrate is confined to the epicardial layer of the right ventricle out-flow tract and free wall [11,12]. The electrograms recorded from the substrate characteristically displayed abnormal high-frequency potentials, expanding the length of the QRS interval and occupying positions at the ST segments. The abolition of such abnormal potentials has been proposed as a promising effective therapy that is able to reverse the type I ECG pattern and control arrhythmia recurrence. If the previous assumption is true, signal processing tools able to quantify the high-frequency content in the QT complexes might non-invasively characterize the arrhythmogenic substrate of BrS patients.

The signal average is the classical method applied to time domain records and has been postulated to have potential utility in the risk stratification of BrS patients [13–18]. However, the signal-averaged ECG is highly dependent on noise and requires long time records, which makes it tedious to use and has never previously helped to provide clear recommendations for patient management. In contrast, we and others previously demonstrated that the continuous wavelet transform may provide efficient analysis of the QRS signal, enabling the identification of late potentials by their subrogate in the frequency domain: the high-frequency content [4,19]. We hypothesized that the high-frequency content of the QT interval may correlate with the high-frequency electrograms founded as the arrhythmogenic

substrate in BrS patients. The latter remains speculative but is strongly supported by the data displayed in our work, which provides an incentive for future research.

4.2. The High-Frequency Content and Patient Prognosis in BrS

Symptoms are major clinical determinants of prognosis in BrS patients, leading to conservative approaches when considering ICD implantation in asymptomatic patients. Despite the possibility of a selection bias of survivors that precludes accurate estimations of the real incidence of SCA/SCD in the general population with BrS [20], most clinical series have demonstrated good prognosis of asymptomatic patients under close follow-up and management of lifestyle, avoidance of drugs with potential adverse effects, and prompt treatment of fever [21]. Under such conditions, the annual incidence of SCA/ICD therapies varies within the range of 0.5% to 1% [22]. However, more than 50% of SCA episodes may occur in previously asymptomatic patients [23], and the cumulative risk has been demonstrated as stable over time [24], which might lead the incidence of arrhythmic events to rise by up to 10% in the next 10 years. This is unacceptable from a clinical point of view and highlights the necessity for clinical improvements in risk stratification in order to prevent rare but devastating events.

Several ECG features may help in risk stratification including fragmentation of the QRS, association with early repolarization syndrome, increased Tpeak–Tend intervals, quantitative measurements on the terminal R wave in lead V1, or the extension of the PR interval [22]. These measurements are widely available in the clinic, as they can be easily performed on a standard ECG. However, the implementation of the automatic quantification of ECG properties might help to overcome subjective interpretation on the ECG tracings and errors occurring when performing hand-made measurements. As presented in our work, BrS patients behave with an increased high-frequency content along the QT interval compared with controls. This difference is highlighted in patients with type II or type III Brugada patterns, which are more challenging ECG presentations. In fact, the presence of increased high-frequency content is an independent predictor of BrS during the drug challenge test, which significantly increases the diagnosis accuracy of other described variables (i.e., age and family history of BrS) and increases the accuracy of syncope as a predictor of events in BrS patients.

In conclusion, our study shows that the high-frequency content of the QT complexes exerts differential behavior in BrS patients that may be linked to the arrhythmogenic substrate and provides additional information for the time domain classification of ECG patterns. Further investigation is needed to establish the roles of these factors as independent predictors of fatal events in the global population with BrS.

5. Limitations

Data regarding the clinical profiles and the characteristics of episodes of syncope were re-checked by direct interviews with the subjects of interest at the time of this study. Thus, we cannot be sure that the patients' memories regarding the conditions of syncope were accurate, which might be an important limitation when concluding the nature of syncope.

This study is observational and retrospective; thus, potential biases may arise because of missing data or inaccurate information collection. A second evaluation with other cohorts would be of interest for external validation. In addition, the number of patients included for analysis was low when attempting the analysis of subgroups (i.e., patients displaying the type III ECG pattern). The latter may have affected appropriate conclusions being reached.

Supplementary Materials: The following are available online at http://www.mdpi.com/2077-0383/8/10/1629/s1.

Author Contributions: D.G.-I.: conceptualization, investigation, and writing—original draft preparation; F.J.d.C.: conceptualization, writing—review and editing, and supervision; F.J.R.: investigation; S.P.: investigation; J.M.R.: writing—review and editing; D.P.: writing—review and editing; J.R.: writing—review and editing; J.M.d.l.H.: writing—review and editing; P.A.: writing—review and editing; J.G.: writing—review and editing; E.C.: writing—review and editing; C.M.: writing—review and editing; D.C.: conceptualization, investigation, writing—original draft preparation, writing—review and editing and supervision.

Funding: Supported in part by grants from the Instituto de Salud Carlos III, Spain (PI18/01268), and the Arrhythmia Section of the Spanish Society of Cardiology to David Calvo PhD.

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Conflicts of Interest: The authors have no conflicts to disclose.

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IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a medical research training arranged by the
Standing Committee on Research Exchange,
International Federation of Medical Students' Associations

14th March, 2019

To whom it may concern,

Hereby **IFMSA-Spain**, the National Member Organization of the International Federation of Medical Students' Associations officially invites the student mentioned below to participate in the research exchange program in the period:

from *01/06/2019 at 30/06/2019*

NAME OF STUDENT: RAMASAMY BALASUBRAMANIAN
DATE OF BIRTH: 10-08-1997
GENDER: Male
NATIONALITY: India
COUNTRY OF ORIGIN: India
PASSPORT NUMBER: Z3210577

The professional part of the program will be organized at the following university clinic/institute. The student will perform a clinical or scientific research project under the supervision of his tutor – one of the staff members. The student will not receive a salary during the period of his exchange period.

PROJECT: Investigation on 1) primary tubular disorders and 2) Growth plate in chronic kidney disease and X-linked hypo
HOSPITAL: Hospital Universitario Central de Asturias (HUCA)
UNIVERSITY, CITY: Spain (IFMSA-SPAIN) - University of Oviedo, Oviedo
HOST COUNTRY: Spain
HOST ORGANISATION: IFMSA-Spain

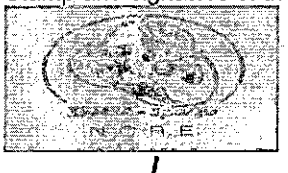
The hosting organization will provide the student with lodging and boarding for the full period of his exchange period.

Any further information regarding the research exchange program can be obtained from the National Officer on Research Exchange:

NAME: Diego Lopez Monge
ADDRESS: Avenue San Mames 5J 2A, 24007, León, Spain
TEL: +34 653321076
EMAIL: ifmsa.nore.spain@gmail.com
Yours sincerely,

Diego Lopez Monge

Stamp and signature of the NORE



medical students worldwide

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

SCORE
Research Exchange

Certificate

This is to certify that the Medical Student

BALASUBRAMANIAN [illegible] SPAIN

from [illegible]

has successfully completed the exchange project entitled

INVESTIGATION ON PRIMARY [illegible] ANOMALIES AND GROWTH PLATE IN CHRONIC KIDNEY DISEASE USING X-LINKED HYPOPHOSPHATEMIA

in the department of PAEDIATRICS

at UNIVERSITY OF OVIEDO (SPAIN) during the period

03/06/2019 - 28/06/2019 under the supervision

of FERNANDO SANTOS

The student has fulfilled the requirements for a research exchange according to the regulations of the Standing Committee on Research Exchange (SCORE) of the International Federation of Medical Students' Associations (IFMSA).

Tutor/Institution

UNIVERSIDAD DE OVIEDO ATTESTED

National/ Local Officer on Research Exchange

ADEMAS

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

CARD OF CONFIRMATION

AF Number
30874

Standing Committee On Research Exchange (SCORE)

Exchange Contract Information	
AF Number	30874
Origin NMO	India (MSAI India)
Exchange is unilateral	No
Contract signed	17/09/2018 Cost: 0

Personal Student Information	
Family name (as written in passport)	Adya
First name (as written in passport)	Vidhi
Sex	Female
Date of birth (dd/mm/yyyy)	10/09/1998
Email	vidhiadya06@gmail.com
Alternative Email	vidhi98adya@gmail.com

Acceptance details	
Accepted in city/LC	Czech Republic (IFMSA CZ) - Charles University in Plzen, Plzen
Project name	Cellular electrophysiology of the heart
Accepted in hospital	Dept of Physiology, Faculty of Medicine in Pilsen, Charles University
Accepted start date (dd/mm/yyyy)	01/06/2019
Accepted end date (dd/mm/yyyy))	30/06/2019

Arrival details	
Do you need pick up by the Hosting Comittee	No
Arrival date and time	12/04/2019
Arrival Location	
Flight/Bus/Train number	
Arrival location details	
Departure date	12/04/2019
Other details	

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

CARD OF CONFIRMATION

AF Number
30874

Standing Committee On Research Exchange (SCORE)

In case of emergency, please contact :

//

Insurance Information

Insurance Company

Policy Number

Contact telephone

Other comments

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IFMSA
International Federation of Medical Students' Associations

OFFICIAL INVITATION LETTER

for a medical research training arranged by the
Standing Committee on Research Exchange,
International Federation of Medical Students' Associations

7th January, 2020

To whom it may concern,

Hereby **HuMSIRC**, the National Member Organization of the International Federation of Medical Students' Associations officially invites the student mentioned below to participate in the research exchange program in the period:

from *03/03/2020 at 31/03/2020*

NAME OF STUDENT: Iyer Jayashree
DATE OF BIRTH: 03-07-1997
GENDER: Female
NATIONALITY: India
COUNTRY OF ORIGIN: India
PASSPORT NUMBER: L1371216

The professional part of the program will be organized at the following university clinic/institute. The student will perform a clinical or scientific research project under the supervision of his tutor – one of the staff members. The student will not receive a salary during the period of his exchange period.

PROJECT: Apoptosis regulation in malign lymphoms
HOSPITAL: Department of Medical Chemistry, Molecular Biology and Pathobiochemistry
UNIVERSITY, CITY: Hungary(HuMSIRC)- Semmelweis University,Budapest
HOST COUNTRY: Hungary
HOST ORGANISATION: HuMSIRC

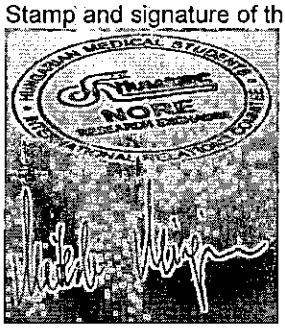
The hosting organization will provide the student with lodging and boarding for the full period of his exchange period.

Any further information regarding the research exchange program can be obtained from the National Officer on Research Exchange:

NAME: Mirjam Miterli
ADDRESS: 4324 Kallosemjen Kossuth street 3/A
TEL: +36703348629
EMAIL: nore@humsirc.hu
Yours sincerely,

Mirjam Miterli

Stamp and signature of the NORE



medical students worldwide

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Aroor Laxminarayana Rao Memorial
Ayurvedic Medical College
KOPPA-577126, Chikmagalur Dist.
Affiliated to Rajiv Gandhi University of Health Sciences & Recognised by Govt. of Karnataka & Central Council of Indian Medicine, NEW DELHI
MANAGED BY : AROOR EDUCATIONAL TRUST (REGD.), KOPPA
OFFICE OF THE PRINCIPAL *e.mail-alnrmamc@yahoo.com website : wwwalnrmamc.com*

S.T.D. :08265
College :221205
FAX :221720
P.G. Centre :221238
Hospital :221884

Ref. No. ALNAC/89/562/2017-18 Date 08 SEP 2017

To,
The Principal,
K.L.E. University's
Shri B.M.K. Kankanwadi Ayurved Mahavidyalaya,
Shahapur, Belgavi-03

Subject: Signing and exchange of MOU .....

Sir,

As per communication based on our mutual understanding on the subject of ***Memorandum of Understanding*** **(MOU)** between two institutes named **K.L.E. University's Shri B.M.K. Kankanwadi Ayurved Mahavidyalaya,** Shahapur, Belgavi and **A.L.N. Rao Memorial Ayurvedic Medical College,** Koppa, a duly signed copy of MOU is sent as attachment herewith.

One copy is retained in our institution while another copy is being dispatched.

On this occasion of collaboration between two esteem institutes of this great nation, we **heartily congratulate** you for your kind and positive gesture. Hopefully our efforts to work jointly for betterment of education and enrichment of working force would add to both institutes.

OFFICE OF THE PRINCIPAL, K.L.E.U. SHRI B.M.K. AYURVEDA MAHAVIDYALAYA, BELAGAVI
DATE: 14/8/17
INWARD NO.: 579

Warm Regards!

A.L.N. RAO MEMORIAL AYURVEDIC MEDICAL COLLEGE KOPPA No. Date

Cordially Yours

PRINCIPAL
A.L.N.Rao Memorial Ayurvedic Medical College,Koppa-577126

CRF
Original - office
Copy - CRF
14/9/17

ATTESTED
Prof. Dr V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

INDIA NON JUDICIAL

Government of Karnataka

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सत्यमेव जयते

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Description of Document	:	Article 12 Bond
Description	:	MEMORANDUM OF UNDERSTANDING
Consideration Price (Rs.)	:	0 (Zero)
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Second Party	:	K L E U SHRI B M K AYURVED COLLEGE BELAGAVI
Stamp Duty Paid By	:	A L N RAO MEMORIAL AYURVEDIC MEDICAL COLLEGE KOPP
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ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Memorandum of Understanding between A.L.N. Rao Memorial Ayurvedic Medical College & P.G. Centre, Kachkal Road, Koppa, Chikmagalur Dist., Karnataka, 577126 and KLEU's Shri B. M. Kankanawadi Ayurved Mahavidyalaya, KLE University, Shahapur, Belagavi, Karnataka, 590003

This Memorandum of Understanding(MoU) (this "Understanding") is executed on 28th day of the Monday month of August 2017 by and between the **A.L.N. Rao Memorial Ayurvedic Medical College & P.G. Centre, Kachkal Road, Koppa, Chikmagalur Dist., Karnataka, 577126,** (here after referred as '**ALN RAO AC KOPPA),** which expression shall, unless repugnant to the subject or context thereof, be deemed to include and mean to its nominees, successors and permitted substitutes or assigns) of the **one PART**

With

KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya, Shahapur, Belagavi, Karnataka, 590003, a premier institute of University having its place of activity in Belagavi, (here after referred as '**KLEU SBMKAM**', which expression shall, unless repugnant to the subject or thereof, be deemed to include and mean to its nominees, successors and permitted substitutes or assigns) on **another PART** either or both of which may be referred to as a "party" or the "Parties" respectively as the context demands.

WHERE AS

A. The **ALN RAO AC KOPPA** and **KLEU SBMKAM** desire to collaborate in the field of intra and interdisciplinary research, drug testing facilities, faculty and student exchange program for the mutual benefit by utilizing the expertise and infrastructure existing in both institutions.
B. Based on the strengths of the **ALN RAO AC KOPPA** and **KLEU SBMKAM,** the ALN RAO AC KOPPA is desirous of collaborating with **KLEU SBMKAM,** which would provide education/ research program/ faculty, drug testing facilities, student exchange/ academic programs for the mutual benefit by utilizing the expertise and infrastructure existing in both institutions.

MoU is to establish hereby a formal understanding of cooperation which is intended to have further the research objectives of each institution and to promote better understanding between the faculty and students of **ALN RAO AC KOPPA** and the faculty and students of **KLEU SBMKAM.**

ATTESTED

Prof. Dr V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

100

Background:

ALN RAO AC KOPPA is a Public Trust registered under Bombay Public Trust Act, 1950. It established in 1987. It has recognized by CCIM for 3 PG Departments with 16 seats and 60 UG seats intake. Institute has good infrastructure for teaching and research with innovative ideology staff.

KLE University is Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9.19/2000-U.3 (A), Re-accredited (2nd cycle) as 'A' Grade by NAAC and placed in Category 'A' by MHRD (GoI). **KLEU's Ayurveda Hospital & Medical Research Center** has been accredited by NABH, the first Ayurvedic institute to get NABH accreditation in Karnataka, **Shri BMK Ayurved Mahavidyalaya** is established in 1933 and is a constituent Institution of KLEU. It has been recognized by CCIM for 11 PG departments with 65 seats and 100 UG seats. It is also conducting PhD program in Ayurveda and Interdisciplinary areas of KLEU PG Certificate Programs on various domains like Vajeekarana, Ksharasutra, Panchakarma, Herbal Drug Research, Ayurgenomics etc. It has good infrastructure for teaching as well has research. Its Central Research facility has been approved as DTL for ASU drugs by AYUSH, Govt. of Karnataka. DAME has been recognized by CCIM as Regional Teacher Training center.

Under this Memorandum of Understanding, the two institutions will proceed to implement the following endeavors and exchanges of materials and personnel.

ARTICLE I: OBJECTIVE

The Parties, subject to the terms of this Memorandum of Understanding and the laws, rules, regulations and national policies from time to time in force, agree to strengthen, promote and develop co-operations in the field of Indian system of medicine (Ayurveda) and Inter Disciplinary Medicine between the two Institutions.

ARTICLE II: AREAS OF COOPERATION

Cooperation shall be carried out, subject to availability of funds and the approval of the competent authority of **ALN RAO AC KOPPA** and **KLEU SBMKAM**, through such activities or programs as:

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

EXCHANGE PROGRAMS:

Faculty and PG & UG students will be exchanged from both Institutes for different programs like workshops, guest lectures, short time training courses, seminars, short term research programs and project works etc. as agreed by both institutes from time to time.

Utilization of research facilities, Joint Research activities

- Faculty and students of both institutes will be allowed, with prior permission, to utilize the research facilities of the Institutes by prescribed nominal fee.
- Both institutions will facilitate the students & faculty by providing access to facilities, guidance of concerned faculty and research staff.
- Both will promote and facilitate inter-institutional, interdisciplinary research and collaborative research projects by faculty and students of the institutions. Short term research projects, summer research projects etc will be allowed.

Continuation of PG/PhD thesis activities

Students of both Institutes will be allowed to have extension of their dissertation/ thesis activities utilizing facilities and expertise in these institutions.

Online meetings/On line Guest lectures

Innovative methods, Information Communication & technology will be used to have better interaction among faculty and students of Institutes through Online guest lectures, group interactions through Skype etc. will be organized.

Research & Development

- Both institutes will work in this area of research & training, especially Drug Analysis – Quality control & Standardization through organizing workshops, brain storming sessions, skill development programs, CME programs collaboratively.
- Facilitation for conduction of tests/analysis available both institutes to each other.
- Submission of samples for analysis for mutual validation of test results
- Promotion of research publications in the journals
- The terms of such mutual cooperation and necessary budget for each specific program will be decided case by case basis upon mutual agreement.
- Each Institute will designate a Liaison Officer to develop and coordinate specific activities or programs.

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ARTICLE III: FINANCIAL ARRANGEMENTS

- The financial arrangements to cover expenses for the identified research activities undertaken within the framework of this Memorandum of Understanding shall be mutually agreed upon by both the Parties on a case-by-case basis subject to availability of funds.

ARTICLE IV: PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

(a) The protection of intellectual property rights shall be enforced in conformity with the national laws, rules and regulations.

(b) Notwithstanding anything in paragraph (a) above, the intellectual property rights in respect of any technological development, and any products and services development, carried out:

(i) Jointly by the parties or research results obtained through the joint activity effort by the Parties, shall be jointly owned by the Parties in accordance with the terms to be mutually agreed upon; and

(ii) Solely and separately by the Party or the research results obtained through the sole and separate effort of the Party, shall be solely owned by the Party concerned.

(iii) The terms and conditions in the execution of the research projects shall be decided on case to case basis.

ARTICLE V: CONFIDENTIALITY

A. Each Party undertakes to observe the confidentiality and secrecy of documents, information and other data received from, or supplied to, the other Party during the period of the implementation of this Memorandum of Understanding or any other agreements made pursuant to this Memorandum of Understanding;

B. Both Parties agree that the provisions of this Article shall continue to be binding between the Parties notwithstanding the termination of this Memorandum of Understanding.

ARTICLE VI: SETTLEMENT OF DISPUTES

Any difference or dispute between the Parties concerning the interpretation and/or implementation and/or application of any of the provision of this Memorandum of Understanding shall be settled amicably through mutual consultation and/or negotiation between the Parties. In case, the dispute occurred between both the parties and if the same is

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not resolved through negotiation or by adopting amicable measures, in that case the matter will be settled through Arbitration and the Arbitrator will be appointed with the mutual consent of both the parties.

ARTICLE VII: ENTRY INTO FORCE, DURATION AND TERMINATION

This understanding shall come into force and take effect from the date first written above and shall be valid for a period of **FIVE (5) YEARS** and may be renewed thereafter by the parties upon mutual consent.

This understanding may be terminated by either party by providing 90 (ninety) days written notice to the other party before the beginning of academic year, and the termination would be effective at the end of the notice period.

And the termination of the Understanding shall be on the understanding that students/ faculty who have already enrolled in any of the courses / research programs as at the time of termination shall remain entitled to complete their respective courses/ research programs and be eligible to appear assessment conducted by the **ALN RAO AC** and **KLEU SBMKAM** conduced to obtain an award. The obligation of the parties shall continue to be in force during such period, notwithstanding any termination of the Understanding.

Now this MOU Witnesses as follows the Roles and Responsibilities of Either Party

- Institutes may provide minimal accommodation for students/ faculty of other institute in their institute on nominal costs, based on availability.
- Students/ faculty have to pay the prescribed fee for the facilities utilized.
- Institutes have to facilitate for easy exchange programs and collaborative work. Administrative hurdles to be cleared at higher level by clear transparent methodology.
- Periodic meeting of co-ordinators will be arranged to have collaboration and co-operation among faculty of two institutes.
- Both parties understand that all financial arrangements will have to be negotiated and will depend on the availability of funds.
- ALN RAO AC and **KLEU SBMKAM** will facilitate for collaborative activities in research and training. Both will arrange facilities for conducting activities including in-house and visiting members from academic institutes.
- ALN RAO AC and **KLEU SBMKAM** shall also arrange to appoint a Coordinator who shall be available at the center where the programs being offered, in order to facilitate proper coordination.

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Coordinators of each center

- At ALN RAO AC, the Principal will oversee the implementation of the Memorandum of Understanding.
- At KLEU SBMKAM, Principal, will oversee the implementation of the Memorandum of Understanding.

Any variation or amendment or addition of / to this Understanding shall be mutually agreed to in writing and executed by or on behalf of each of the parties, the **ALN RAO AC** and **KLEU SBMKAM.**

This Understanding represents the entire understanding as to the subject matter hereof and supersedes any prior understanding between the parties on the subjects matter hereof.

In witness whereof, the parties hereto have executed this understanding as of the date first above mentioned.

Signed for and on behalf of Principal ALN Rao Memorial Ayurvedic Medical College Koppa	Signed for and on behalf of Principal KLE University's Shri B.M.K. Ayurveda Mahavidyalaya, Belagavi, Karnataka
Signature:	Signature:
Name: Dr. SANJAYA.K.S	Name: Dr. T.S. Sreenivasa Prasad PRINCIPAL
Designation: PRINCIPAL A.L.N.Rao Memorial Ayurvedic Medical College,Koppa-577126	Designation: K.L.E. University's Shri B. M. Kankanwadi Ayurved Mahavidyalaya Shahapur-BELAGAVI-03

Signed in presence of Memorandum of Understanding Initiators:

1. Dr. Vedantam Sridhar, CRF_Chief Coordinator
2. Dr. Prashant Kumar Jha, Head, QC Lab., ALNRMAMC

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KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed-to-be-University)
JAWAHARLAL NEHRU MEDICAL COLLEGE
Belagavi – 590 010, Karnataka (India)
DEPARTMENT OF PATHOLOGY

JNMC Office: 0831 – 2471350
Phone: 0831-2473777- Extn. 4051 / 4052
FAX NO. 91- 0831- 2470759
Website : http/www.jnmc.edu
Email : patho@jnmc.edu
Email : jnmc@sancharnet.in

Date: 18-09-2018

To,

Dr. Jayaram N. Iyengar
Managing Director
Anand Diagnostic Laboratory (A Neuberg Associate)
Neuberg Anand Reference Laboratory
Anand Tower, 54, Bowring Hospital Road,
Shivajinagar, Bangalore - 560001 India

Subject: Posting of PG students from J. N. Medical College to Anand Diagnostic Laboratory

Dear Dr. Jayaram,

As per your email dated 22-06-2018, kindly permit the following PG students in Pathology (M.D) from J. N. Medical College, Belagavi to attend a posting at the Anand Diagnostic Laboratory for a period of 15 days in the month of October 2018, i.e. from 1-10-2018 to 15-10-2018.

The names of the PG students are as follows:

1. Dr. Krutika Joshi
2. Dr. Naresh Kulkarni
3. Dr. Ruchi Singh
4. Dr. Saumya Gaur

Dr. Karthik Srevatsa, PG student of Pathology is posted in the month of November 2018.

Thank you for your co-operation.

With kind regards

J.N. Medical College BELAGAVI Department of Pathology

Dr. Ramesh Chavan
Professor and Head,
Department of Pathology,
JNMC, Belagavi- 590010

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सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA121602379458985
Certificate Issued Date	:	20-Feb-2020 02:14 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ YAMAKANMARDI/ KA-BL
Unique Doc Reference	:	SUBIN-KAKACRSFL08346657278006305
Purchased by	:	REGISTRAR KLE ACADAMY OF HIGHER EDU AND RESH BGM
Description of Document	:	Article 12 Bond
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	REGISTRAR KLE ACADAMY OF HIGHER EDU AND RESH BGM
Second Party	:	KARNATAKA CANCER THERAPY AND RESH INSTITUTE HUBLI
Stamp Duty Paid By	:	REGISTRAR KLE ACADAMY OF HIGHER EDU AND RESH BGM
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

For Yamakanmardi Urban Credit Society Ltd., Dr. Bela...

Authorised Signatory

RS 100

Please write or type below this line

Renewal of Memorandum of Understanding (MoU) between KLE V.K. Institute of Dental Sciences (KLEVKIDS), Belagavi and the Karnataka Cancer Therapy and Research Institute (KCTRI), Hubballi

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified ...

ATTESTED

Prof. Dr. V.A.KOTHIWALE
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Memorandum of Understanding (MoU) between KLE VK Institute of Dental Sciences (KLEVKIDS), Belagavi and the Karnataka Cancer Therapy and Research Institute (KCTRI), Hubballi

The MoU between KLEVKIDS, under KLE Academy of Higher Education and Research (KAHER) and KCTRI Hubballi was established on the 28th September 2011. The objective of this MoU was primarily the academic collaboration between the two institutes. The previous renewal was on 1st October 2015 and was for three years. The present renewal is from 1st October 2018 to 30th September 2023, for a period of five years.

The following aspects have been agreed mutually by both the institutes:

1. **Research Collaboration:**

Both the institutions work together and contribute in research works especially involving Oral Oncology and execute the activities agreed upon, in publications, reports, informational materials, messages or any other means used to disseminate information on these activities.

2. Faculty Exchange:

The faculty members identified by the KLE VK Institute of Dental Sciences shall be officially permitted to visit KCRTI to enable them to keep in touch with the specialty / specialties, update themselves with the knowledge and skills in their fields and also to undertake research work at KCTRI.

3. Joint Conference, Symposia and Workshops:

Both the Institutions being centers of higher education at Post-Graduate and PhD levels, it is mutually agreed that they share the Organizing Committee of the Conferences, Workshops or symposia which are based on common topics like Oral Oncology, Reconstructive Surgery, etc.

4. Sharing of Knowledge Resources:

The faculty members of both the institutions shall develop knowledge and resources which include projects and content, mutually deemed useful for exchange.

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Prof. Dr. V.A.KOTHIWALE
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5. Faculty and post-graduate training and treatment of patients with head neck cancer: KCTRI shall permit post-graduate students and faculty members of KLEVKIDS for training in head and neck cancer surgery. If necessary, the patients of KLEVKIDS can avail the benefits treatment under appropriate government schemes at KCTRI for treatment of head and neck cancer and reconstruction of head neck tumor ablation defects with advanced surgical techniques like micro-vascular free tissue transfer.

6. There shall be no financial commitment from either of the institutions for any of the activities or programs.

IN WITNESS WHEREOF THE RESPECTIVE INSTITUTIONS HAVE DULY EXECUTED THIS MEMORANDUM THE DATE FORESAID

For **KLE Academy of Higher Education and Research, Belagavi**

Prof. (Dr) V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

KLE Academy of Higher Education and Research
Belagavi -590010
Karnataka, INDIA

In the presence of:
Dr. Asha Kaila
Principal
KLEVK IDS, Belagavi
Signature:

For **Karnataka Cancer Therapy Research Institute, Hubballi**

Dr B. R. Patil
Chairman and Chief Surgical Oncologist
Dr. B. R. PATIL M.S.
CHAIRMAN
The Karnataka Cancer Therapy & Research Institute
Navanagar, Hubballi
Karnataka Cancer Therapy & Research Institute
Hubballi, Karnataka, INDIA

In the presence of:
Dr. Manjula Hugar
Administrative officer
KCTRI, Hubli
Signature:
Administrative Officer
Karnataka Cancer Therapy and Research Institute, HUBLI-25

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Prof. Dr. V.A.KOTHIWALE
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Memorandum of Understanding (MoU) between KLE VK Institute of Dental Sciences (KLEVKIDS), Belagavi and the Karnataka Cancer Therapy and Research Institute (KCTRI), Hubballi

The MoU between KLEVKIDS, under KLE Academy of Higher Education and Research (KAHER) and KCTRI Hubballi was established on the 28th September 2011. The objective of this MoU was primarily the academic collaboration between the two institutes. The previous renewal was on 1st October 2015 and was valid for three years. The present renewal is from 1st October 2018 to 30th September 2023, for a period of five years.

Outcomes of MoU (from 28-09-2013 to 1st October 2018):

1. **Number of cases of oral cancer that were operated:**
   So far 20 cases of oral cancer have been operated by Dr Sidramesh Muttagi, from the department of oral and maxillofacial surgery, KLEVKIDS, Belagavi, on honorary basis. These patients were from poor socio-economic background and were operated under BPL schemes.
2. **PhD thesis:**
   Dr Sidramesh Muttagi is doing his PhD under the guidance of Prof (Dr) A S Godhi, former Principal and Professor of Surgery, JNMC Belagavi, on squamous cell carcinoma of gingiva-buccal sulcus. The surgical specimens of the patients operated at KCTRI Hubballi were grossed at the department of Oral and Maxillofacial Pathology, KLEVKIDS, Belagavi. This has contributed to the progress in the research in the field of Oral Oncology, especially in understanding the disease process and associated clinic-pathological variables. This has opened new avenues for the research concerning the molecular biology of oral squamous cell carcinoma. Also, the postgraduate students in the department of Oral and Maxillofacial Pathology are getting trained in grossing of onco-surgical specimens, which happens in very few institutes in the country. Apart from this, some rare tumors like oral malignant melanoma and papillary cystadenocarcinoma of buccal mucosa have been reported from our institute.

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3. **Post Graduate dissertations:**

Based on the tissue samples and surgical specimens of oral cancer there are six post graduate dissertations the are ongoing in the department of Oral and Maxillofacial Pathology, KLEVKIDS, Belagavi. One PhD thesis and a post graduate dissertation that was based on oral oncology were completed by December 2019.

4. **Research projects and publications:**

There are two short term studies on oral cancer in the department of Oral and Maxillofacial Pathology. They are based on the research collaboration from KCTRI. The two years of research collaboration between the two institutes has been successful in bringing out three publications in the international peer reviewed journals. An ICMR project entitled "reasons for diagnostic and therapeutic delay in oral cancer patients in Northern Karnataka: a multicenter study" has been completed by Dr Anusha C, under the guidance of Dr Sidramesh Muttagi. An article entitled "clinic-pathological factors affecting lymph node yield in Indian patients with locally advanced squamous cell carcinoma of mandibular gingiva-buccal sulcus patients has been published in the Indian Journal of Cancer. Another publication entitled "clinicopathological predictors of extent of cervical lymph node metastases in locally advanced squamous cell carcinoma of mandibular gingivobuccal sulci has been published in Journal of Scientific Society, Volume 5, 2018.

5. **Fellowship awarded:**

Dr Sidramesh Muttagi was awarded Indo-American Cancer Association (IACA) Travelling Fellowship in the year 2016 for his work and research contribution in Oral Oncology, working at KLEVKIDS and being associated with KCTRI. He completed the fellowship program at the prestigious Memorial Sloan Kettering Cancer Center, New York, USA. The objectives of this fellowship were to learn the state of art techniques in managing oral cancer and reconstruction of oral defects, under the guidance of Prof (Dr) Jatin P Shah, a renowned head neck cancer surgeon. He is looking forward to improve the outcomes of surgery for the patients of oral cancer, practicing at KLE Dr Prabhakar Kore Hospital and MRC, Belagavi.

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6. **Postings of post graduate students:**

The post graduate students from the department of Oral and Maxillofacial Surgery and from the department of Oral Medicine and Radiology of KLEVKIDS are posted at KCTRI. This gives an opportunity for the students to learn and understand the concept of oral cancer surgery and various advanced therapy for oral cancer.

7. **Conferences and Workshops:**

Eminent faculties from KCTRI have been invited guest speakers for scientific programs conducted at KLE VK Institute of Dental Sciences, Belagavi. Dr B. R. Patil, a renowned surgical oncologist with vast experience in Oral Oncology has been instrumental in training post graduate students and has participated as faculty in various scientific programs hosted by VK Institute of Dental Sciences, Belagavi. A pre-conference workshop held during National Triple O symposium on 16th February 2017, on cadaveric neck dissection was a successful program highlighting the steps in neck dissection for oral cancer.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
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KLE Academy of Higher Education
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MEMORANDUM OF UNDERSTANDING

BETWEEN

RASAYU CANCER CLINIC, B-1, AMRUT KUMBHA, LAKSHMI PARK SOCIETY, NAVIPETH PUNE

AND

KLE UNIVERSITY'S

SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA

SHAHAPUR, BELAGAVI, KARNATAKA.

For

Establishment of Cancer OPD at KLE Ayurveda Hospital And Research Activities

MEMORANDUM OF UNDERSTANDING

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

This Memorandum of Understanding ("**MoU**") dated this 11th day of July 2017

by and between:

KLEU's Shri B M Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda hospital, Belagavi is a leading institute in offering super speciality quality health care in field of Ayurveda in India., having its office at Nathpai circle, Shahapur, Belagavi (here in after referred to as '**KLE Ayurveda hospital'**) which expression shall unless it be repugnant to the context or meaning there of shall be deemed to mean and include its successors and permitted assigns) of the **One Part**

AND

Rasayu cancer clinic having its place of business at B-1 Amrut kumbha,Lakshmipark society, Navipeth Pune .(here in after referred to as '**RCC'** which expression shall unless it be repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **Other Part**

KLE Ayurveda hospital and RCC shall be individually here in after referred to as '**Party**' and collectively as '**Parties**'.

Where as

A. 'KLE Ayurveda hospital' is a Teaching Ayurveda hospital providing vide range of super-specialty healthcare facilities to Patients.

B. 'RCC' is engaged in specialised Ayurveda based cancer therapies to cancer patients and cancer survivors. These facilities include but are not limited to offering Ayurveda consultation, preparing Ayurveda medicines and dietary supplements for these patients, Panchakarma therapies, offering diet, yoga and psychology consultation.

C. The parties are interested in exploring possible opportunities of establishing a mutually cooperative and beneficial relationship, including the carrying out of Projects relevant to their respective capabilities in India.

D. KLE Ayurveda hospital and RCC, confirm and understand that this MOU is not intended to provide and set out any contractual terms binding or otherwise

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governing the terms and conditions or the manner of conduct of any Projects and that may necessarily require the Parties to:

- share relevant information on a confidential basis with the aim and objective of identifying their requirements, needs and capabilities;
- establish a working relationship between themselves (which is targeted to the parties' specific needs);
- establish Projects which may be of mutual benefits and interest;
- Determine the details of Projects, their scope and purview, Project work plan, funding of the Project, their rights, duties and obligations in relation to the Project and its outcome.

For the purposes of each Project, the Parties shall enter into separate Agreements.

For the purposes of this MOU, "**Project**" shall mean a collaboration relating to Establishing specialty cancer OPD for development of Standard Treatment Protocol's in Cancer Management through specialized Ayurveda consultation and therapies for cancer patient at the premise of KLE Ayurveda hospital, Shahapur, Belagavi.

1. SCOPE OF THE MOU

1.1 The Parties will co-operate to:

(a) Establish facilities for offering specialized Ayurveda consultation to cancer patients which includes offering Ayurveda, yoga, diet and psychological consultation; preparing personalized medicines and dietary supplements for cancer Patients.

(b) Conduct cancer awareness drives, campaigns and lectures for common public and patients.

(c) Conducting various oncology based training programs for Medical students and professionals.

(d) Conduct an annual review of current and future Projects approximately one (1) week prior to the anniversary of the execution of this MOU.

1.2 Subject to the terms and conditions of any Collaboration Agreement agreed to and executed, each Party will have the right, in any field related to the Project or otherwise, to:

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(a) conduct business or research independently, whether or not with third parties;

(b) continue existing commitments, or make new ones;

(c) Exploit or otherwise take advantage of its intellectual property.

2. COLLABORATION AGREEMENT

2.1 The Parties acknowledge and confirm their intention to negotiate and settle the terms and conditions of a Collaboration Agreement in respect of each Project.

2.2 The parties agree that the ownership of the intellectual property rights arising out collaboration will be jointly shared between RCC & KLE. Publications, Authorship rights of involved Doctors/Consultants will be protected. Freedom for conducting individual OPD and Research & Developing new protocols on their own.

2.3 Each Collaboration Agreement will include provisions relating amongst other things to:

(a) A Project plan pursuant to which the Project will be carried out which will include information pertaining to technical objectives, statement of work, deliverables, schedule, decision gates, resource requirements and costs;

(b) Funding arrangements for the Project;

(c) Holding by the Parties of periodic Project review meetings to assess the management and the progress of the Project and the status of any expenditure;

(d) Exploitation of Intellectual property and rights arising from the same including their protection, enforcement and commercialization.

(e) Commercial arrangements between the KLE Ayurveda hospital and RCC.

2.4 The Parties agree, acknowledge and confirm that for any agreement to be binding on them, it must be in writing and shall be executed by a duly authorized representative of each of the KLE Ayurveda hospital and RCC.

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2.5 KLE Ayurveda hospital will provide basic infrastructure/facilities required for offering patient care which include consultation, treatment procedure, inpatient hospitalisation, investigations, dispensing medicines and dietary supplements and collecting treatment charges. KLE will establish speciality Cancer OPD for Ayurveda management. KLE will provide OPD facility in it to RCC for their expert consultancy as per mutual understanding and permit to prescribe the proprietary/ Research formulations of RCC and protect the confidentiality of RCC.

2.6 KLE Ayurveda hospital will make necessary arrangements for offering medical care and consultation by qualified Ayurveda physician trained in RCC Treatment protocol, to patients approaching for treatment in the collaborative RCC and KLE cancer OPD. Consultant from KLEU in Speciality Cancer OPD will have freedom to plan for different protocols and medications based on the clinical case otherwise RCC standard protocol will be used.

2.7 KLE Ayurveda hospital will make necessary arrangements to avail expert medical opinion or to refer the patient to appropriate medical facilities in case of any emergencies.

2.8 KLE Ayurveda hospital will make arrangements to procure medicines manufactured by Ayurved Rasayani, as required for the collaborative RCC and KLE cancer OPD.

2.9 RCC will offer appropriate training in Ayurveda oncology to doctors deputed by KLE Ayurveda hospital. The number of doctors at a given point of time will not exceed two (2).

2.9 RCC will periodically depute a trained qualified Ayurveda physician so as to provide direct consultation to patients approaching the collaborative RCC and KLE cancer OPD. This doctor will visit KLE Ayurveda hospital at least once in a month. The travel expenses for this visit will be totally beared by RCC.

2.10 KLE Ayurveda hospital will be conducting regular awareness activities about the collaborative RCC and KLE cancer OPD. These activities includes Awareness programs, lectures, pamphlets, banners, newspaper articles and Radio broadcast. KLE Ayurveda hospital will bear all the expenses of such activities.

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2.11 If required for the betterment of patient, RCC will make necessary arrangement to provide online/skype consultation to these patients in Belgaum.

2.12 The responsibility for providing best possible treatment for patient and ensuring his wellbeing lies entirely with the treating physician.

3. REPRESENTATIVE

3.1 For the term and purposes of this MOU, each party shall appoint a designated representative ("the **Representative**").

3.2 The Representative of the appointing Party will be responsible for:

a) managing, overseeing or coordinating that Party's relationship with the other Party;

b) identifying any commercial issues that arise between the Parties and refer them to the **Competent Authority** within the Representative's organization;

c) discussing any issues arising out of this MOU or a Collaboration Agreement with the Representative of the other party; and

d) Co-coordinating the exchange of information between the Parties.

3.3 The Representatives designated at the time of signing this MOU by the parties are:

(a) for KLE Ayurveda hospital:

Name: Dr B S Prasad.

Designation: Medical Director

Email: kleayurvedahospital@gmail.com

Mob. 9448569289.

(b) for RCC

Name: Dr. Avinash Kadam

Designation: Administrator.

Email: avinashk@rbpl.co.in

Mob. 9970259583

4. CONFIDENTIAL INFORMATION

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

4.1 **Definition:** As used herein **Confidential Information**" shall mean and include all information and data which has been provided/disclosed/shared by RCC to KLE Ayurveda hospital prior and post the execution of this MOU and/or the Collaboration Agreement either written or oral or in any other form or manner of communication or which has been acquired or will be acquired by either Party such as designs, drawings, specifications, technical information, documents and know-how, designs, manufacturing processes, ideas, data, financial information and other technologies, whether patentable, copyrightable or susceptible to any other form of protection. The terms and existence of this MOU, the fact that Confidential Information has been shared and/or made available, that discussions or negotiations pertaining to the technology are taking place between the Parties shall also be considered Confidential Information for the purposes of this MOU.

4.2 **Purpose:** The Parties shall use the Confidential Information strictly and solely for the purposes the Confidential Information is provided under this MOU and none other.

4.3 **Ownership:** The Parties hereby understand, acknowledge, and confirm that the Confidential Information is a valuable trade secret owned by each Party and which retains all right, title, and interest in and unto the same. Neither Party shall have any right, title and interest in the Confidential Information of the other Party. By virtue of either Party disclosing the Confidential Information, no license to such Confidential information or any Intellectual Property rights owned by that Party is or are granted to the other Party. Neither Party shall directly or indirectly, through its directors, employees or agents, at any point of time, do any acts, things or deeds that may prejudicially affect the proprietary right, title and interests of either Party in and unto the Confidential Information.

4.4 **No Warranties:** At no point of time shall either Party be responsible for any loss or damages which may be suffered by the Party receiving the Confidential Information or for that matter by its customers or any third parties on account of or arising from the use of the Confidential Information. Neither Party makes any representations or warranties of any kind, whether expressed or implied as to the accuracy or completeness of the Confidential Information.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
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KLE Academy of Higher Education
and Research, BELAGAVI

4.5 **Use of Confidential Information:** Each Party may use the Confidential Information for the purposes stated in Clause 4.2 above only. Each Party recognizes that this MOU imposes an affirmative duty on the other Party to hold such information in confidence and to protect it from dissemination to and use by any and all unauthorized parties. In the absence of any prior written consent neither Party shall copy, reproduce or disclose the Confidential Information to any third party in any manner whatsoever.

4.6 **Further Responsibility**: The Parties agree and undertake to use the same degree of care to protect the confidentiality of the Confidential Information as it would exercise to protect its own trade secrets and information but in no case less than a reasonable degree of care. Each Party may grant access to the Confidential Information to its directors, officers, employees, advisors and consultants ("**related parties**") who have a clear need to know, for purposes of this MOU and shall advise such related parties of the existence and terms of this MOU and of its obligations of confidentiality herein. MoU shall lead to standard clinical protocols in management of cancer which will be asset of both the institutions. Each organisation will have the right to continue or utilize the products, protocols developed during the collaboration even after termination of MoU.

4.7 **Return of Confidential Information**Promptly following the request of either Party the receiving Party will return to the disclosing Party or certify in writing to the disclosing Party as to the destruction of (without retaining any copy in any form or manner) all Confidential Information including copies and extracts thereof as may have been or will be furnished as by the disclosing Party to the receiving Party. But the Hospital records/ data and pharmacy data will be archived to oblige hospital/ pharmacy regulations.

4.8 **Remedies:** The Parties acknowledge, understand and confirm that the disclosing Party is the proprietor of the Confidential Information and that any unauthorized disclosure, misappropriation or unauthorized use of such Confidential Information by the receiving Party in any manner whatsoever will cause serious irreparable loss and harm to disclosing Party. The receiving Party expressly agrees that the disclosing Party shall be entitled to seek injunctive and other

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

equitable relief against it to prevent the breach or further breaches of any of its confidentiality obligations under this MOU and which it will not dispute by challenging the jurisdiction of the competent Courts where injunctive or equitable relief is being sought at by the disclosing Party.

5. TERMINATION AND AMENDMENT

The term of this MOU is a period of one (1) year from the date of execution. The MOU will be automatically renewed for a further period of one (1) year unless one Party notifies the other Party in writing 30 days in advance that they do not wish to renew the MOU at the completion of the annual review of current and future projects.

5.1 his MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one (1) month written notice to the other.

5.2 A Collaboration Agreement made pursuant to clause 2 of this MOU shall survive termination or expiration of this MOU.

5.3 This MOU may be amended only by an agreement in writing between the Parties and not otherwise.

6. GENERAL

6.1 KLE Ayurveda hospital and RCC agree that each of them is free to undertake R&D and business projects on their own or in conjunction with third party, and that the Parties will co-operate only in circumstances where each of them agrees if co-operation is for their mutual benefit and each is satisfied that the specific provisions covering their co-operation are appropriate and will not adversely or prejudicially affect their interests.

6.2 With the exception of Clause 4 herein, this MOU is not binding and the Parties do not intend that it or any part of it be binding. It serves only as a record of the understanding between the Parties' intentions pending possible execution of a Collaboration Agreement as contemplated by Clause 2 herein.

6.3 Nothing in this MOU will oblige or cast any obligation upon either Party to enter into a Collaboration Agreement with the other Party or to conduct any Project.

7. This MOU constitutes the entire understanding between the Parties regarding the subject matters contained herein. Any prior agreements,

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KLE Academy of Higher Education
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commitments or negotiations concerning the subject matters herein are superseded.

8. The headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the provisions contained therein.

9. If one or more provisions of this MOU are held to be illegal or unenforceable,
such provisions will be limited or excluded to the minimum extent required so that this MOU will otherwise remain enforceable in accordance with the remaining terms.

10. The rights of the Parties hereto shall not be prejudiced or restricted by any
indulgence or forbearance extended to the other party and no waiver by the parties hereto of any breach of the other party of any of the terms hereunder shall operate as a waiver in respect of any subsequent breach. No variation of this MOU shall be effective unless it is in writing and duly signed by both parties.

11. **FORCE MAJEURE:** Neither party shall be liable for any delay in or failure of discharging respective obligations under this MOU caused by occurrence beyond the control of KLE Ayurveda hospital or RCC as the case may be, including but not limited to fires, floods, explosions, power shortage, failure/breakdown of UPS/DG set/computer, acts of GOD, hostility, acts of public enemy wars, insurrections, riots, strikes, lockouts, sabotage. Either parties shall promptly but not later than 10 days of the commencement there of notify the other in writing of such contingency and prove that such is beyond the control and affects the implementation of this MOU adversely and materially. If such contingency continues beyond 30 days both the parties, agree to discuss and agree upon an equitable solution.

12. **ARBITRATION:** For any interpretation of clauses in this MOU or in case of any dispute during implementation, such matter will be jointly discussed by representative of KLE Ayurveda hospital and RCC. In case of disagreement, the matter would be referred to the International Centre for Alternative Dispute Resolution (ICADR, an autonoMoUs organization

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working under the aegis of the Ministry of Law and Justice, Govt. of India) New Delhi-110 070. ICADR decision would be binding on both parties.

IN WITNESS, WHERE OF, the parties have executed this MOU as of the date first above written

SIGNED AND DELIVERED BY	**SIGNED AND DELIVERED BY**
Registrar KLE University	**RCC**
through its Authorized Signatory	**through its Authorized Signatory**
Signature	**Signature** Yogesh Bendale
Name of person signing MOU	**Dr Yogesh Bendale**
Designation	**Chairman and MD (RBPL)**
in the presence, of	in the presence, of Dr. Anand Patil
in the presence, of Sreedhar (Dr. Vedantam Giridhar)	in the presence, of Dr. Neha Mali

ATTESTED

KLE Academy of Higher Education and Research, BELAGAVI

Scinva Chemicals and Pharmaceuticals Pvt Ltd

CIN : U24239KA2013PTC069657

Memorandum of Understanding between KLE University's College of Pharmacy, Bengaluru and Scinva Chemicals and Pharmaceuticals Pvt Ltd, Bengaluru

This MOU is made and signed and made effective on 21st July 2017 between the Department of Pharmaceutics, KLE University's College of Pharmacy (KLEUCP), with the principal Address at 2nd Block, Rajainagar, Bangaluru-560 010, and Scinva Chemicals and Pharmaceuticals Pvt. Ltd.(SCPPL), with the address at #No.121/20, Kumbalagodu Industrial Area, 1st Phase, Behind KEB Power Station, Bengaluru - 560074.

As per the agreement KLEUCP and SCPPL have entered into a mutual understanding for undertaking product developmental projects at the Department of Pharmaceutics, KLEUCP, Bengaluru.

The charges for the consultancy service rendered by KLEUCP would be Rs 2500/- per day. The above prices will hold good for the financial years 2017-18.

Dr. Narashima Murthy
Director
Scinva Chemicals and Pharmaceuticals Pvt. Ltd

Dr H.N.Shivakumar
Professor and Head
KLEU's College of Pharmacy, Bengaluru

Bangalore

Registered Office : No 213/1, [illegible] 8th cross, BHEL [illegible] Rajarajeshwari Nagar, Bangalore 560098

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Scinva Chemicals and Pharmaceuticals Pvt Ltd

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The charges for the consultancy service rendered by KLEUCP would be Rs 2500/- per day. The above prices will hold good for the financial years 2017-18.

Narshima murthy

Dr. Narashima Murthy
Director
Scinva Chemicals and Pharmaceuticals Pvt. Ltd

Dr U.N.Shivakumar
Professor and Head
KLEU's College of Pharmacy, Bengaluru

Bangalore

Registered Office: No.213/1, Nandi Teja 5th cross, BHEL Extension, Rajarajeshwari Nagar, Bangalore -560098.

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Institute of Physiotherapy

A constituent unit of

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(Deemed-to-be-University)

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

KIPT/ 963/18 Date: 19/03/2018

To,

The Registrar,

KLEAHER,

Belagavi – 590010

Sub: Regarding MoU with Dr Randoll Institut Germany

Sir,

With reference to above mentioned subject, I wish to request you to kindly approve the draft for MoU to be signed between KLE Institute of Physiotherapy and Dr Randoll Institut Germany. This is for your consideration and needful.

Thanking you

Yours Truly

Principal

BELAGAVI.

Address : JNMC Campus, Nehru Nagar, Belagavi-590010, Karnataka, India

Ph : 0831-2473906, Fax : 0831-2474727

Website: http:/www.klekipt.edu.in E-mail:kipt@india.com

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING (MoU)

Between

KLE INSTITUTE OF PHYSIOTHERAPY
A constituent unit of
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed-to-be-University established u/s 3 of the UGC Act)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka India

and

DR. RANDOLL INSTITUT
Non-Profit Organization for Matrix Research and Education
Lortzingstr .26
81241 Munich
Germany

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA36159734759745Q
Certificate Issued Date	:	05-Apr-2018 01:22 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BELGAUM27/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKAKSFCL081856560386186Q
Purchased by	:	KLE INSTITUTE OF PHYSIOTHERAPY BELAGAVI
Description of Document	:	Article 12 Bond
Description	:	MEMORANDUM OF AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KLE INSTITUTE OF PHYSIOTHERAPY BELAGAVI
Second Party	:	DR RANDOLL INSTITUT NON PROFIT ORG MRE GERMANY
Stamp Duty Paid By	:	KLE INSTITUTE OF PHYSIOTHERAPY BELAGAVI
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Authorised Signatures
Aadhar Multi-Purpose Soutnard Sahakari
Nyt. Shivabasav Nagar, BELAGAVI.

Please write or type below this line

AGREEMENT

KLE Institute of Physiotherapy is a university institute for Physiotherapy education, (Established under Section 3 of the UGC Act, 1956) having its registered office at Nehru Nagar, Belagavi, Karnataka – 590010, India, hercinafter referred to as KIPT, WHEREAS KIPT is well known and reputed institute conducting Physiotherapy education and is engaged in research activities., which expression shall unless repugnant to context-in-which it is used, includes its successor and administration) of the FIRST PART

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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AND

This Agreement is executed at _____ on this ____ day of December, 2017 by and between Dr. Randoll Institut – Non-profit organization for Matrix Research and Education, established on 06th June, 2013, having its registered office at Lortzingstr .26 81241 Munich Germany. Dr. Randoll invented a new tool for treatment of pain and restricted mobility in human body by Matrix Rhythm Therapy. Dr. Randoll Institut is a training and research institute extending post professional education related to Matrix Rhythm Therapy and catering to aspirant from India and abroad in the Matrix Rhythm Therapy discipline with treating and training. Dr. Randoll Institut is already conducting basic and advanced certification courses in Matrix Rhythm Therapy (MaRhyThe) which is well taken globally, Dr. Randoll Institut - hereinafter referred to as "DRI" which expression shall, unless it be repugnant to the context or meaning thereof, to be deemed to include its successors, executors, administration and assignee, being of the SECOND PART;

KLE and DRI individually referred to herein as a party and collectively as the parties.

WITNESSETH AS FOLLOWS:

Whereas it is highly desirable to develop multi-disciplinary training and research through involvement and integration of diverse but relevant disciplines through synergy and knowledge sharing and ensure dissemination of knowledge to all corners of the country;

Both parties felt that a sustained, synergetic and effective collaboration between DRI and KLE will enhance strength and add value to, the efforts of each party.

AND WHEREAS both institutions have agreed to work together and establish academic collaboration with each other to enhance the quality of Physical Therapy education and training.

NOW, THEREFORE, IN CONSIDERATION OF MUTUAL COVENANTS AND PREMISES CONTAINED HEREIN, THE PARTIES ENTER INTO THIS AGREEMENT AND AGREE THAT:

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and Research, BELAGAVI

The Parties therefore agree on Objective of creating an institutional framework for enriching scientific endeavors in mutually agrees fields of education and training with following broad Objectives

A) Broad Objectives:

1. Develop synergetic collaborations in a resource-sharing and knowledge-sharing environment in various areas of science and technology;
2. Share expertise in training and other academic activities through joint organization of events, joint guidance of students, exchange of faculty and students;
3. Develop research programs for funding by national and international agencies;
4. Design and develop outreach activities and programmes for various mutually identified goals of **DRI** and **KLE;**
5. Develop collaborations in laboratories and equipment's sharing as well as publications, patents (if any);
6. To encourage instruction, writing and research in the field of Physical Therapy;
7. To set educational goals to commit clinicians to lifelong learning in the art and science of Physical Therapy;
8. To create awareness among physical therapists, the contemporary practice patterns in Physical Therapy;
9. To apply aspects of evidence in their practice patterns, to justify the effectiveness of intervention;
10. To offer a structure in examination and treatment of dysfunctions within the scope of physical therapy;

B) **AREAS OF COLLABORATION:**

1. Dr. Randoll institute is a non-profit organization at Munich, Germany.
2. Dr. Randoll Institut works on research and development based on the Matrix Concept according to Dr. Ulrich Randoll.
3. Dr. Randoll Institut welcomes University, Academic institutes and Individuals with Academic and research interest in Matrix Concept.
4. Being a Non-Profit Organization, Dr. Randoll Institut is not involved in any commercial activities.

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Prof. Dr. V.A. KOTHIWALE

5. Dr. Randoll Institut supports research into Matrix Rhythm Therapy and Matrix Concept of Scientific interest and practical importance for the health.
6. Dr. Randoll Institut will not provide any financial assistance, sponsorships for the research activities, publication or presentation
7. Dr. Randoll Institut will not provide infrastructure or tools for the activities. Individuals/Institute participating in any research/ academic activity will have to organize required infrastructure/ facilities/tools etc. at their own resources.
8. Any donations or funds organized or received by the individual or the institute participating in the research will be responsible for the use, misuse, and accounting or auditing of the financial responses, Dr. Randoll Institut will not be responsible for any financial activities.
9. Academic Institute/individual doing the research will share all the information, majors, and outcomes of the research, clinical studies, and trials etc with Dr. Randoll Institut.
10. Dr. Randoll Institut authorizes to use name and logo of Dr. Randoll Institut and Dr. Ulrich Randoll for authorized academic and research activities.
11. Individuals / research institute doing clinical research, study will be responsible for taking or obtaining any clinical permission (clearance), approval from ethical committees, and consent from the participants in the study of their own. Dr. Randoll Institut will not be responsible for any claims of any kind arise.
12. Dr. Randoll Institut will provide only academic support for the research, clinical studies, trials and educational program required.
13. Dr. Randoll Institut has certified instructors authorized to conduct, organize and provide academic and therapeutic training for application of Matrix Rhythm Therapy (MaRhyThe). Participants in the clinical research will have to attend workshops for the successful outcomes of the research.
14. The research institutes or individuals under this understanding will maintain the secrecy of some important information shared between Dr. Randoll and themselves. Any information will not be published or shared with other institute, organization or individual without permission of Dr. Randoll Institut. Sharing such information will be an offence.

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15. This understanding can be terminated with prior notice of 6 months and intimation by both the parties.
16. For any individual/institute this understanding is valid for a period of 3 years.

C) **Mode of Operation:**

Both parties will provide necessary support for effective implementation of the agreement/ MoU within then institutional rules and procedures

1. This MoU shall be effective from the date it is signed by the two Parties.
2. Within the broad framework of the MoU, KLE and DRI can develop joint research, academic or scientific programme, exchanges, development of facilities, etc.
3. The activities under this MoU shall be coordinated, monitored and recorded by an Internal Coordination Committee constituted of member nominated by both parties; **each organization will appoint a coordinator** who will organize joint meeting at regular intervals at mutually agreed locations and maintain records of agreements, work plan and progress.
4. The visitors will be bound by the rules and regulations as well as code of conduct of the host institution.
5. The Internal Coordination Committee will also formulate the procedure for exchange of students, faculty and other visitors, in accordance with the rules of the host participating institutions as defined in preamble.
6. The mode and quantum of resource sharing will be decided based on recommendation of the Coordination Committee on the case to case basis, **Subject to approval of competent authority as required.**
7. The Coordination Committee will formulate action plans at its meetings and communicate for information and necessary approvals by the concerned authorities.
8. In case of transfer/installation of equipment's and other capital assets, an additional document of commitments shall have to be signed by the receiving institute.
9. LIAISON AND SUPERVISION: Dr. Ulrich Randoll of Dr. Randoll Institut and The Principal of the Faculty of Physiotherapy, KLE will

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Prof. Dr. V.A. KYATANAVAR
KLE Academy of Higher Education
and Research, BELAGAVI

look after the operation, supervision and follow up of the arrangements in MOU.

D: Obligations of the parties:

1. In accordance with the clause C 3-4 as above, each party shall nominate a Coordinator and members to the Coordination Committee within 15 days of signing the MoU.
2. Each Party shall provide all necessary support at its disposal and as allowed by its institutional rules, for implementing this MoU effectively.
3. DRI will recognize KLE Faculty as Guides/co-guide as per the provision of pertaining ordinance for collaborative research and vice versa.
4. KLE and DRI will jointly train and guide the students enrolled for collaborative training program/course on yearly basis.
5. Faculties of MaRhyThe; **Dr. Ulrich Randoll, (Inventor) and/or any certified Instructor** from the Dr. Randoll Institut will serve as lead faculty in the operation of the MaRhyThe.
6. KLE will provide all the infrastructural, logistic and facilities for the smooth conduction of MaRhyThe in its campus.
7. The KLE shall share knowledge and facilities within the institutional rules and:

a. Provide access to libraries, archives, research laboratories and other facilities.
b. Provide access to instruments and equipment as mutually agreed.
c. Encourage joint discussions on new information and scientific development.
d. Share knowledge/information and publication/ magazines/literature as may be essential for academic pursuit.

E: Duration and termination:

1. This MOU shall remain in force initially for a period for three years, however, thereafter; it may be renewed automatically for an extended period unless any of the parties seeks termination in writing.
2. This MoU may be terminated prior to expiry of the MoU as indicated above with three months' notice and with the written consent of the heads of the two organizations provided both parties agrees that the

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

completed.

3. Termination of this MoU between the participating components shall not terminates the agreements entered between the parties and with any third parties which the parties may have entered into in executing the agreements under this MoU; the parties shall continue to obtain the benefits of the MoU and agreement. After termination of MoU neither of the parties will be responsible for any losses, financial or otherwise, which the other party may suffer. Upon termination of expiry of the MoU, parties are obliged to keep the information confidential, as agreed above.

F: Data Sharing and Intellectual Property Rights:

1. No rights in Industrial and / or Intellectual Property (Including without limitation, letters, patent, registered design, software copyrights, trademark, and copyright) owned by the parties on the date of signature of this MoU and independently developed on their part are hereby granted by the owning Party to the other party, nor shall any such rights be deemed to be granted except specified by owning party. Each party will have the exclusive ownership and rights on the independently developed intellectual property after signing of MoU.
2. The Intellectual Property Rights in respect of joint project will be decided on case-to-case basis. Parties will mutually decide on sharing of required information by way of joint publication in journals and seminars or workshops etc. All publications resulting from the collaboration between the parties will be mentioned in the scientific reports of the either Party.
3. Sharing of any data generated (either observational or computational) under the aegis of this MoU shall be as per the provision of the specific project/program.
4. Each Party shall duly acknowledge the contribution/involvement of other party in each activity in its bulletins/publications/media release/ outreach and any other official communication.
5. Every member of both Parties in any activity under the aegis of this MoU shall abide by the prevailing policies of Govt. of India with respect to classified information/data. During the tenure of this MoU

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Registrar
KLE Academy of Higher Education
and Research

and for Five years thereafter, Parties undertakes on their behalf and on behalf of their employees or representatives or associates to maintain strict confidentiality and prevent disclosure thereof to any third party, all the information and data exchanged or generated during the operation of MoU.

6. Ethical Clearance for joint Projects will be provided by KLE Institute of Physiotherapy.

G: GENERAL PROVISION:

1. Neither Party shall assign, or in any manner, transfer its interest or any part thereof in this MoU, except to wholly owned subsidiaries and agreed explicitly to that effect in writing. This MoU shall be binding on and inure to the benefit of the Parties hereto and their respective heirs, personal representatives, successors and assignees; and,
2. This MoU constitutes the entire understanding between the Parties relating to the subject matter hereof and supersedes and cancels all previous or collateral MoUs, negotiations, commitments, representations or understandings between the Parties with respect to this MoU, and the subject matter hereof. If any of the provisions of this MoU are determined to be invalid under applicable law, they are, to that extent, deemed omitted. The invalidity of any portion of this MoU shall not render any other portion invalid; and,
3. No amendments or modifications of this MoU shall be valid unless they are made in writing by both the Parties or their authorized representative and specifically stating the same to be an amendment of this MoU. The modifications/changes shall be effective from the date on which they are made or executed unless otherwise agreed to.
4. This MoU is not intended to constitute, create, give effect to, or otherwise recognize a joint venture, partnership, or formal business organization, of any kind, and the rights and obligations of the Parties shall be only those expressly set forth herein. Nothing in this MoU shall be construed to grant either Party the right to make commitments of any kind for or on behalf of the other without the other's prior written consent. At all times contemplated herein, and both shall remain independent entities, each responsible for its own

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employees. Each Part assumes no responsibility to the other fro costs, expenses, risks, and arising from the efforts of the party.

H: FORCE MAJEURE

Neither **Parties** shall be held responsible for non-fulfillment of their respective obligations under the **MoU** duration to the exigency of one or more of the Force Majeure events such as, but not limited to, the acts of God, War, Flood, Earthquake, Strikes, Lockouts, Epidemic, Riots, Civil commotions etc., provided on the occurrence and cessation of any such event the **Party** affected thereby shall give a notice in writing to the other Party within 30 (Thirty) days of such occurrence or cessation. If the Force Majeure conditions continue beyond 6 (six) months, the Parties shall jointly decide about the future course of action.

J. GOVERNING LAWS AND DISPUTES RESOLUTION

1. This **MoU** shall, in all respects, be governed by and construed in all respects in accordance with the laws of the Republic of India.
2. This **MoU** is to create a framework for enriching scientific endeavors in mutually agreed fields of research through collaboration in developing and implementing new academic and research programs and faculty and students exchange. Hence any question, doubt or dispute arising out of the interpretation of any term or usage herein or on the implementation and functioning of the various understanding forming a part of this **MoU** shall be resolved by the Heads of the two organizations or their authorized representatives for the purpose mentioned herein by discussions and negotiations base on consensus in the spirit of developing and strengthening the mutual relationships.
3. Any unresolved dispute if any, shall be referred to Sole Arbitrator in accordance with Arbitration and Conciliation Act, 1996 and rules framed thereof. Arbitrator shall be appointed on mutual consent of Parties. Arbitration shall be conducted at Belagavi in English language; the decision of arbitrator so reached shall be final and binding on both the parties.

ATTESTED

Prof. Dr. [illegible]

K: SEAL OF THE PARTIES

In within whereof, the PARTIES represented by their authorized representatives, set forth their hand on this the day, month and year first states above agreed and accepted this **MOU** to be signed in the presence of the following witnesses: IN WITNESS WHEREOF, each of the parties has caused this agreement to be executed by its duly authorized authorities as of date written above.

Witness 1 Sanjiv Kumar

Name: Sanjiv Kumar

Address: _____

For and on behalf of KLE

Registrar

Dr. V. D. Patil

Seal

Witness 2

Name: Dr M.S Ganachari

Address: _____

For and on behalf of DRI

Director

Dr. Ulrich Randoll

Seal

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Composite Regional Centre (CRC)

(Under Administrative Control of National Institute for the Empowerment of Persons with Intellectual Disabilities, Secunderabad)
Department of Empowerment of Persons with Disabilities (Divyangjan)
Ministry of Social Justice & Empowerment, Government of India

No. CRC-DVG/ACAD./AWR/04/49 31-May-2018

To

Dr. Sanjiv Kumar,
The Principal, KLE Academy of Higher Education and Research of Physiotherapy
JNMC Campus, Nehru Nagar, BELAGAVI - 590 010, Karnataka
Email: kipt@india.com Phone. No: 831-2474727, 831- 2473906

Sub: Requesting collaboration for organizing awareness program, short term training programs

Sir/Madam,

Greetings from Composite Regional Centre, Davanagere.!

Composite Regional Centre (CRC) is a service modality initiated by the Dept. of Empowerment of Persons with Disabilities (Divyangjan), Ministry of Social Justice & Empowerment at Davanagere in Feb 2017. CRC's Objective is to strengthen the services for Persons with Disabilities in Karnataka.

We are in the process of scheduling Awareness Programs, Short Term Training Programs for higher education students, higher education teachers, health care professionals working for the benefit of Persons with Disabilities in Karnataka.

S. No	Training Program Name	Expected Participants	Days of Training per Program	No. of Participants	No. of Programs
1	Awareness Programs	College Students/ Teachers/ Health Care Professionals	1 Day	100	10
2	Early Identification and Intervention Program for Physical Disabilities	Anganwadi workers / ANMs / VRWs / MRWs / Nursing Students etc.,	2 Days	30	1
3	Identification and Management of Life Style Disorders	Health Care Professionals	2 Days	30	1

We look forward for collaboration from your Institute for organizing the above programs. In the awareness programs the officials from CRC, Davanagere will handle the sessions which includes orientation about CRC services, Rights of Persons with Disabilities Act 2016, Govt. Schemes & Services for Persons with Disabilities etc., We have budgetary provision to provide snacks, lunch & certificates for the participants. If interested kindly contact us by email to director.crcdvg@gmail.com for more details.

Thanking you,

Yours faithfully

(Sh. Shaik Yaseen Shareef)
Director In-charge

Address: CRC, Devaraj URS Layout,
B-Block, Davanagere, Karnataka – 577 006

Tele: 08192-233465
Email: director.crcdvg@gmail.com

ATTESTED

Prof. Dr. V. A. KORISHETTAR
PRINCIPAL
KLE Academy of Higher Education and Research, BELAGAVI

KLE Academy of Higher Education and Research
EMPOWERING PROFESSIONALS Deemed-to-be-University

Institute of Physiotherapy

A constituent unit of
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed-to-be-University)

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

KIPT/130/18

Date: 08/06/2018

To,
Sh. Shaik Yaseen Shareef
Director In- Charge
Composite Regional Centre (CRC)
Devaraj URS Layout, B-Block,
Davanagere, Karnataka – 577006.

Subject: collaboration for organizing awareness programme, short term training programs

Sir/Madam,

Greetings from KAHER Institute of physiotherapy, Belagavi.

We thank you for extending your willingness to collaborate with our institution, for organizing awareness and short term training programs.

We are happy to associate with you and provide assistance by deputing our distinguished faculty to train the expected participants in early identification and Intervention Program for Physical Disabilities and Identification and management of Lifestyle Disorders Program.

Thanking you,

Yours truly,

Dr. Sanjivkumar
Dean & Principal,
KLE Institute of Physiotherapy,
Belagavi-590010, Karnataka, India

Address : JNMC Campus, Nehru Nagar, Belagavi-590010, Karnataka, India
Ph : 0831-2473906, Fax : 0831-2474727
Website: http:/www.klekipt.edu.in E-mail:kipt@india.com

Prof. Dr. V.A. KOTHIWALE

KLE Academy of Higher Education and Research, BELAGAVI

KLE University's

Institute of Physiotherapy

JNMC Campus, Nehru Nagar, Belagavi- 590010, Karnataka, India.
Ph:0831-2473906, Fax:0831-2474727,
Website: http:/www.klekipt.edu.in E-mail:kipt@india.com
(A constituent unit of KLE University [formerly known as KAHE], Belagavi)

KIPT/ 656/18 Date: 12/2/2018

To,
The HOD,
Dept of Physiotherapy,
Tata Memorial Cancer Hospital,
Dr Ernest Borges Road, Parel,
MUMBAI,
Maharashtra 400012

Sub: Regarding One month posting for PG students in your institute.

Sir/Madam,

With reference to the subject cited above, I would like to request you to permit 5 PG students [Oncology Physiotherapy] to undergo one month posting & training in your institute from 06/03/2018 to 06/04/2018. Following are the students:

1] Ms. Anjali Parab

2] Ms. Manaz Rayani

3] Ms. Oshin Mathias

4] Ms. Snehal Birje

5] Ms. Snehal Deelip Thakur

Kindly do the needful.

Thanking you in anticipation, kindly acknowledge the receipt of the same.

Yours truly,

Principal,
KLE, Institute of Physiotherapy,
Belagavi.

BELAGAVI

ATTESTED

PROF. Dr. V. A. KOTHIWALE

KLE Academy of Higher Education and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING (MoU)

Between

KLE INSTITUTE OF PHYSIOTHERAPY

A constituent unit of
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER)
(Deemed-to-be-University established u/s 3 of the UGC Act)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka India

and

CAPRI INSTITUTE OF MANUAL THERAPY (CIMT)

179, Jagriti Enclave, Vikas Marg
Delhi, India Pin 110092

ATTESTED

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING (MoU)

Between

KLE INSTITUTE OF PHYSIOTHERAPY

A constituent unit of
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and

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179, Jagriti Enclave, Vikas Marg
Delhi, India Pin 110092

ATTESTED

Prof. Dr. V.A.KOTHIWALE

KLE Academy of Higher Education
and Research, BELAGAVI

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

[illegible] No.	:	IN-KA48376741398443P
[illegible] Issued Date	:	14-Dec-2017 01:03 PM
[illegible] Reference	:	NONACC (FI)/ kaksfcl08/ BELGAUM27/ KA-BL
[illegible] Doc. Reference	:	SUBIN-KAKAKSFCL0848880017549229P
[illegible] by	:	KAHER KLE INSTITUTE OF PHYSIOTHERAPY
[illegible] of Document	:	Article 12 Bond
[illegible]	:	MOU
[illegible] Price (Rs.)	:	0 (Zero)
[illegible] Party	:	KAHER KLE INSTITUTE OF PHYSIOTHERAPY
[illegible] Party	:	CAPRI INSTITUTE OF MANUAL THERAPY
[illegible] Duty Paid By	:	KAHER KLE INSTITUTE OF PHYSIOTHERAPY
[illegible] Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatures /
Aadhar Multi-Purpose Souhard Sahakari
Nyt. Shivabasav Nagar, BELGAUM.

Please write or type below this line

AGREEMENT

KAHER Institute of Physiotherapy is a constituent unit of the KLE Academy of Higher Education and Research, Deemed-to-be-University, Established under Section 3 of the UGC Act, 1956) having its registered office at Nehru Nagar, Belagavi, Karnataka – 590 010, India, hereinafter referred to as KAHER, WHEREAS KAHER is well known and reputed institute conducting physiotherapy education and engaged in research activities., which expression shall unless repugnant to context in which it is used, includes its successor and administration) of the FIRST PART

ATTESTED

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.

[illegible]OTHWALE

KLE Academy of Higher Education and Research, BELAGAVI

AND

This agreement is executed at _____ on this ___ day of _____, 2017 between Capri Institute of Manual Therapy (A unit of Capri Health Care & Research Institute Pvt Ltd.), established on 16th May 1997 having its registered office at A 64, Hans Apartment east Arjun Nagar, CBD Maidan, Shahdara, Delhi 110032 and working office at 179, Jagriti Enclave, Vikas Marg, Delhi, India Pin 110092.,Whereas Capri institute of Manual Therapy is a manual therapy institute extending post professional education related to manual therapy and catering to aspirant from India and abroad in the physical therapy discipline, CIMT has already conducted more than 200 graduate course in manual therapy which is well taken globally, hereinafter referred to as "CIMT" which expression shall, unless it be repugnant to the context or meaning thereof, to be deemed to include its successors, executors, administration and assignee, being of the SECOND PART;

KAHER and CIMT individually referred to herein as a party and collectively as the parties.

WITNESSETH AS FOLLOWS:

Whereas it is highly desirable to develop multi-disciplinary training and research through involvement and integration of diverse but relevant disciplines through synergy and knowledge sharing and ensure dissemination of knowledge to all corners of the country;

Both parties felt that a sustained, synergetic and effective collaboration between CIMT and KAHER will enhance strength and add value to, the efforts of each party.

AND WHEREAS both institutions have agreed to work together and establish academic collaboration with each other to enhance the quality of Physical Therapy education and training.

ATTESTED

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

B AREAS OF COLLABORATION:

1. As a part of collaborative activities, the CIMT and KAHER will jointly offer a three months training program followed by Certificate in Orthopedic Manual Therapy (COMT) intended for practicing physical therapists and interns in physiotherapy. Complete details of the training program and certification methodology are given in the Annexure one.
2. The CIMT will process enrollment and registration and offer its expertise through conducting lectures and skill development sessions by CIMT & KAHER IPT faculty, in orthopedic manual physical therapy fulfilling the need for completion of this program including evaluation for certificate.
3. Faculty of Physiotherapy of KAHER will fulfill the needs of the program through enrolment and registration, infrastructure, supervision and award of Certificate through the office of faculty of physiotherapy.
4. Three months training programme of COMT will be conducted four time a year.
5. Faculty of CIMT and KAHER will scrutinize the eligibility of the candidates and prepare final list of candidates registered for the training program. Each batch will have around 30-50 candidates but not exceeding 50 candidates. The candidates shall have to complete the certificate program maximum within 1 year from the time of enrolment.

C Mode of Operation:

Both parties will provide necessary support for effective implementation of the agreement/ MoU within then institutional rules and procedures

1. This MoU shall be effective from the date it is signed by the two Parties.

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PROF. DR. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

10.2 The Director, Capri Institute of Manual Therapy will coordinate with Principal, Faculty of Physiotherapy, KAHER, for completing the above said duties.

10.3 Proposed Fee for supervision will be paid to Principal of KAHER as mentioned in annexure II by CIMT.

Obligations of the parties:

1. In accordance with the clause C-4 as above, each party shall nominate a Coordinator and members to the Coordination Committee within 15 days of signing the MoU.
2. Each Party shall provide all necessary support at its disposal and as allowed by its institutional rules, for implementing this MoU effectively.
3. CIMT will recognize KAHER Faculty as Guides/co-guide as per the provision of pertaining ordinance for collaborative research and vice versa.
4. KAHER and CIMT will jointly train and guide the students enrolled for collaborative training program/course.
5. Faculties of CIMT; **Dr. Deepak Kumar,** _MSPT, FIAP, PhD (Mulligan Concept) and **Dr. Bhini Semwal (PT)** MPT, MIAP, COMT, CMP from the Capri Institute of Manual Therapy will serve as lead faculty along-with other faculties of CIMT in the operation of the COMT. In case of inability of any of the above faculty, the Capri Institute of Manual Therapy will depute suitable alternate faculty.
6. A non-refundable fee per candidate and its sharing and collection pattern for the entire Certificate programme along with break-up of money is mentioned in Annexure-II which shall form part of the present agreement. Respective share of Fee will be directly collected by each party from the course participants at the time of course enrolment. This fee can be renewed from time to time after mutually agreed by both parties, No Financial commitment from either organization except as per Annexure II shall be assumed unless a formal approval/acceptance to that effect has been accorded through signed documents by both the organizations.

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Faculty from the CIMT and KAHER will evaluate the candidates for their eligibility to receive the certificate along with the commencement of successive batch for the program.

The KAHER shall share knowledge and facilities within the institutional rules and:

Provide access to libraries, archives, research laboratories and other facilities.

Provide access to instruments and equipment as mutually agreed.

Encourage joint discussions on new information and scientific development.

Share knowledge/information and publication/ magazines/literature as may be essential for academic pursuit.

Duration and termination:

This MOU shall remain in force initially for a period for three years. However, where after, it may be renewed automatically for an extended period unless any of the parties seeks termination in writing.

This MoU may be terminated prior to expiry of the MoU as indicated above with three months' notice and with the written consent of the heads of the two organizations provided both parties agrees that the instruction and eligibility for Certificate of all enrolled students will be completed.

Termination of this MoU between the participating components shall not terminates the agreements entered between the parties and with any third parties which the parties may have entered into in executing the agreements under this MoU; the parties shall continue to obtain the benefits of the MoU and agreement. After termination of MoU neither of the parties will be responsible for any losses, financial or otherwise, which the other party may suffer. Upon termination of expiry of the MoU, parties are obliged to keep the information confidential, as agreed above.

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KLE Academy of Higher Education
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GENERAL PROVISION:

1. Neither Party shall assign, or in any manner, transfer its interest or any part thereof in this MoU, except to wholly owned subsidiaries and agreed explicitly to that effect in writing. This MoU shall be binding on and inure to the benefit of the Parties hereto and their respective heirs, personal representatives, successors and assignees; and,
2. This MoU constitutes the entire understanding between the Parties relating to the subject matter hereof and supersedes and cancels all previous or collateral MoUs, negotiations, commitments, representations or understandings between the Parties with respect to this MoU, and the subject matter hereof. If any of the provisions of this MoU are determined to be invalid under applicable law, they are, to that extent, deemed omitted. The invalidity of any portion of this MoU shall not render any other portion invalid; and,
3. No amendments or modifications of this MoU shall be valid unless they are made in writing by both the Parties or their authorized representative and specifically stating the same to be an amendment of this MoU. The modifications/changes shall be effective from the date on which they are made or executed unless otherwise agreed to.
4. This MoU is not intended to constitute, create, give effect to, or otherwise recognize a joint venture, partnership, or formal business organization, of any kind, and the rights and obligations of the Parties shall be only those expressly set forth herein. Nothing in this MoU shall be construed to grant either Party the right to make commitments of any kind for or on behalf of the other without the other's prior written consent. At all times contemplated herein, and both shall remain independent entities, each responsible for its own employees. Each Part assumes no responsibility to the other fro costs, expenses, risks, and arising from the efforts of the party.

ATTESTED

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

OF THE PARTIES

whereof, the PARTIES represented by their authorized representatives; set forth their hand on this the day, month and year first above agreed and accepted this **MOU** to be signed in the presence of following witnesses: IN WITNESS WHEREOF, each of the parties has caused this agreement to be executed by its duly authorized authorities as written above.

1

For and on behalf of KAHER

R. DAKSHA DIXIT

Signature : Dakshq

Registrar
Dr. V. D. Patil
Seal

REGISTRAR
KLE Academy of Higher Education
and Research, BELAGAVI

2

Chanchal

Signature : Chanchal

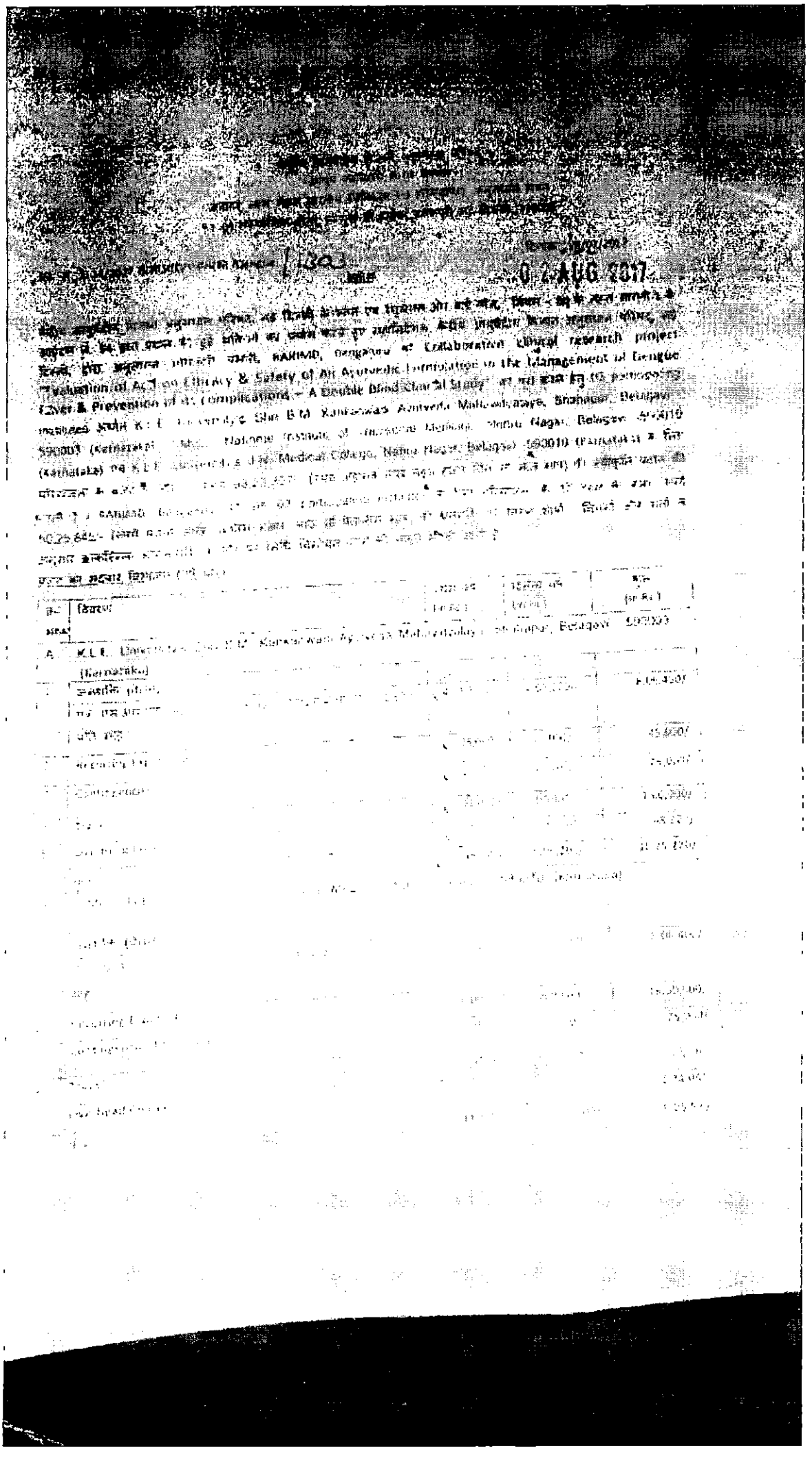
For and on behalf of CIMT

Director
Dr. Deepak Kumar
Seal

ATTESTED

12

PROF. S. V. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI



क्र. संख्या	विवरण	प्रथम वर्ष (in Rs.)	द्वितीय वर्ष (in Rs.)	कुल (in Rs.)
C	K.L.E. University's J.N. Medical College, Nehru Nagar, Belagavi -590010 (Karnataka)			
1	जनशक्ति (वेतन) [illegible] 26,000 + 20% [illegible] = 33,600/- [illegible]	4,03,200/-	4,03,200/-	8,06,400/-
2	Recurring Expenditure	25,45,830/-	23,50,000/-	48,95,830/-
3	Contingencies Miscellaneous	15,000/-	10,000/-	25,000/-
4	Travel	85,000/-	85,000/-	1,70,000/-
5	Overhead Charges (5%)	[illegible]	1,44,862/-	2,94,862/-
	कुल	31,59,830/-	29,93,062/-	61,92,092/-
	Grand Total	50,25,845/-	47,97,462/-	98,23,307/-

नियम एवं शर्तें -

1. [illegible] CCRAS Research Policy के अनुसार [illegible]।
2. [illegible] BARIMD, Bengaluru [illegible] after fulfilling the requisite formalities of MoU and EC approval as per CCRAS Research Policy [illegible] participating institutes [illegible] K.L.E. University's Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi - 590003 (Karnataka), ICMR - National Institute of Traditional Medicine, Nehru Nagar, Belagavi -590010 (Karnataka) एवं K.L.E. University's J.N. Medical College, Nehru Nagar, Belagavi -590010 (Karnataka) [illegible] Belagavi [illegible] CCRAS Research Policy के अनुसार [illegible]
3. The progress of the project in accordance with approved timeline and deliverable should be submitted to the Council HQs on monthly basis in the prescribed format (Annexure-6 to CCRAS Research Policy). The final report should be sent in the prescribed format (Annexure-7 to CCRAS Research Policy) within two months from the date of completion of the project [illegible] participating institutes [illegible] BARIMD, Bengaluru [illegible]
4. [illegible] principles laid down in Chapter 6 of the General Financial Rules 2017 titled "Procurement of Goods and Services" [illegible]।
5. Separate account will be maintained for the project by all the participating institutes and BARIMD Bangalore. Record of expenditure may be kept separately by respective PI for audit purpose.
6. [illegible]
7. The funds released and spent will be subject to audit by government audit system [illegible] the Investigator from [illegible] should submit the audited utilization certificate and audited statement of expenditure along with [illegible] through [illegible] to Council [illegible] through BARIMD Bangalore.
8. [illegible]
9. [illegible]
10. [illegible]

ATTESTED

BT/IN/DBT-MRC/DFID/SSG/16/2018-19

Government of India
Ministry of Science & Technology
Department of Biotechnology

Block 2, 7th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 09.05.2019

Admin Order

Sanction of the President is hereby accorded under Rule 18 of the Delegation of Financial Power Rules, 1978 for the implementation of the UK-India Global Research Partnership (GRP) joint research project titled **"CRADLE-4: Can Reduction of Adverse pregnancy outcomes occur with planned DeLivery vs. Expectant management in pre-eclampdia?"** by **Dr. Shivaprasad S Goudar**, KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka for a period of **3 years** at a total cost of **Rs.168.80 Lakhs (Rupees One Crore Sixty Eight Lakhs Eighty Thousand Only)** for the Indian component of the project on the terms and conditions as detailed hereunder:

2.0 PROJECT TITLE :
"CRADLE-4: Can Reduction of Adverse pregnancy outcomes occur with planned DeLivery vs. Expectant management in pre-eclampdia?"

2.1 Investigators :

Indian Investigators:

Principal Investigator	**Dr. Shivaprasad ~~S Goudar,~~** KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka
Co-Principal Investigators	**Dr. Mrutyunjaya Bellad,** JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Mrityunjay Metgud, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Sangappa Dhaded, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Manjunath Somannavar, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Umesh Charantimath, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka

UK Investigator:

Principal Investigator	**Professor Andrew Shennan,** Women's Health, King's College London
Co-Principal Investigators	**Prof. Lucy Chappell,** Women's Health, King's College London
	Prof. Jane Sandall, Women's Health, King's College London
	Mr. Paul Seed, Women's Health, King's College London
LIC PI:	**Prof. Bellington Vwalika,** MRC/UVRI Unit, Uganda

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Prof Dr V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

2.2 Project Aims & Objectives:

i) To determine whether in low and middle income country populations (LMIC) planned early delivery for women with pre-eclampsia after 34 weeks of gestation will reduce a composite outcome of maternal morbidity and mortality without increasing adverse neonatal outcomes compared to current practice.

ii) To determine the impact to the intervention on short-term perinatal outcomes including adverse events related to planned delivery (e.g. increased NNU admission from RDS) and expectant management (e.g. stillbirths and NNU admissions related to growth restriction/asphyxia).

iii) The impact of the intervention on other secondary short-term outcomes for the mother will also be determined such as the number of women that are referred to hospital for delivery, the length of hospital stay and the mode of delivery.

iv) To determine how the intervention is influenced by context including political and cultural environment in each setting and explore the experiences of women and their families. The development work in Phase 1 will identify potential barriers to the intervention in each context and potential solutions.

2.3 Project Duration:

The duration of the project is **three years** from the date of this Admin order.

2.4 Project Cost:

The estimated cost for the Indian component of the project for three years is as under:

(Rs. in Lakhs)

S. No.	Head	Year I	Year II	Year III	Total
A.	**Non-recurring**				
1.	Equipment Desktop (Nos. 2)	1.50	0.00	0.00	1.50
	Total (A)	**1.50**	**0.00**	**0.00**	**1.50**
B.	**Recurring**				
1.	Consumables	1.15	0.35	0.35	1.85
2.	**Manpower**				
a.	Project Administrator (Sr. RS) - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 60,000/- fixed per month	5.40	7.20	5.40	18.00
b.	Data Coordinator (RO)- Consultant (Scientific Technical/Medical/Non Medical) @ Rs. 1,00,000/- fixed per month (will work only 15% in the month)	1.35	1.80	1.35	4.50
c.	Data Manager & Network Manager- Consultant (Scientific technical/Medical/Non Medical) @ Rs. 1,00,000/- fixed per month (will work only 20% in the month)	1.80	2.40	1.80	6.00

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Prof. Dr. V.A.KOTHIWALE
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d.	Data Entry Operator – Grade C @ Rs. 31000/- fixed per month	2.79	3.72	2.79	9.30
e.	Field Monitoring (LHV) – Junior Medical Officer (2 Nos.) @ Rs. 60000/- in the 1st and 2nd year and Rs. 75000/- in the 3rd year (will work only 50% in the month)	5.40	7.20	6.75	19.35
f.	Training Coordinator (Sr. SN) - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 1,00,000/- fixed per month (will work only 20% in the month)	1.80	2.40	1.80	6.00
g.	Officer Secretary (LDC) – Data Entry Operator – Grade C @ Rs. 31000/- fixed per month	2.79	3.72	2.79	9.30
h.	Budget Manager - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 60000/- fixed per month (will work only 15% in the month)	0.81	1.08	0.81	2.70
i.	Field Assistant - Data Entry Operator – Grade C (4 Nos.) @ Rs. 31000/- fixed per month	11.16	14.88	11.16	37.20
	Total Manpower	**33.30**	**44.40**	**34.65**	**112.35**
3.	**Travel**				
	Domestic	3.35	3.10	1.80	8.25
	International	2.50	4.00	3.50	10.00
	Local Hospitality for visiting Scientist	1.00	1.00	1.00	3.00
	Total	**6.85**	**8.10**	**6.30**	**21.25**
4.	Contingency	0.25	0.25	0.25	0.75
5.	Overhead	2.00	2.00	2.00	6.00
6.	Other Expenses	3.10	5.90	3.10	12.10
7.	Training & FGD & Expenditure	9.00	2.00	2.00	13.00
	Total (B) (1+2+3+4+5+6+7)	**55.65**	**63.00**	**48.65**	**167.30**
	Total (A+B)	**57.15**	**63.00**	**48.65**	**168.80**

3. **HEAD OF ACCOUNT:**

Non-Recurring expenditure involved is debitable to:

Demand No.85	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance For Research and Development
60.200.29.17.35	:	Grant for creation of capital assets 2019-20

Recurring expenditure involved is debitable to:

Demand No.85	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance For Research and Development
60.200.29.17.31	:	Grant in aid General 2019-20

ATTESTED

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Submission of formal agreement with DBT:

4. A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee organization(s) on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/ installment will be made only after signing of MoA by the grantee organization(s) and its acceptance by DBT. In case of NGO or Private organization(s), signed MoA is mandatory before the first release. Format of the MoA alongwith annexures (as mentioned below) to be submitted with MoA is enclosed here with:
   a. Detailed project activities to be placed at **Annexure I**
   b. Details of funds to be placed at **Annexure-II**
   c. The other terms and conditions governing this sanction to be placed at **Annexure- III**

Conditions for submission of UC/SE and Progress Report:

5. (a) The grantee organization(s) will maintain separate bank account for the project and the entire amount of grant will be kept in an interest bearing account. The interest so earned should be reported to DBT in the Utilization Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the organization(s) and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

   (b) The Registrar, KLE Academy of Higher Education and Research, Belagavi would be responsible for submission of financial year wise Statements of Expenditure (SoE), Utilization Certificate (UC), Assets Acquired Certificate, Manpower Due Drawn Statement in prescribed DBT formats to DBT in respect of grants released in this project from time to time.

   (c) While submitting Utilization Certificate and Statement of Expenditure, the organization has to ensure submission of supporting documentary evidences with regard to purchase of equipment/capital assets and manpower certificate with qualification (including details of national level qualifying exam) details. Subsequent release of grants under the project shall be considered only on receipt of the said documents.

   (d) The grantee organization(s) shall submit up to date progress report at the end of each financial year in the proforma prescribed by DBT, and as and when required by DBT.

Conditions for acquiring Assets (Non-recurring grant):

6. (a) A transparent procurement procedure in line with the provisions of General Financial Rules 2017 will be followed by the organization(s) under the appropriate rules of the grantee organization(s) while procuring capital assets sanctioned for the above mentioned project and a certificate to this effect will be submitted by the Grantee organization(s) immediately on receipt of the grant.

   (b) DBT reserves sole rights on the assets created out of grants, Assets acquired wholly or substantially out of government grants (except those declared as obsolete and unserviceable or condemned in accordance with the procedure laid down in GFR 2017), shall not be disposed of without obtaining the prior approval of DBT.

   (c) The equipment/instrument shall have to be purchased within **nine (9) months** from the date of release of the capital grant. Fresh permission shall have to be sought from DBT in the event the organization fails to purchase the equipment/instrument within the prescribed period of **nine (9) months** from the date of release of sanctioned amount.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Conditions of Domestic/International Travel:

7. (a) No International Travel will be undertaken from the sanctioned project grant for the purpose other than the specified in the project.

(b) As per MoF instructions, it has been decided that in all cases of air travel both domestic and international, where the Government of India bears the cost of air passage, the investigator/research staff concerned may travel only by Air India. For travel to stations not connected by Air India, the investigator/research staff may travel by Air India to the Hub/Point closest to their eventual destination, beyond which they may utilize the services of another airline which should also preferably be an alliance partner of Air India. The tickets are to be booked in terms of guidelines issued under DoE OM. No. 19024/22/2017-EIV dated 19th July, 2017.

Other conditions:

8. PI's of DBT sponsored projects can consider appointment of manpower as per the Department of Science and Technology's O.M. No. SR/S9/Z-08/2018 dated 30.01.2019. In case investigator(s) inclined to explore provisions other than the stipulated herewith (i.e. institutional norms, ICMR norms, ICAR norms etc), prior approval from DBT shall be obtained in writing before appointment of manpower.

9. The data sharing among the partnering and any other organization needs to be accomplished without compromising on the national integrity, security business opportunities and IPR norm.

10. It is mandatory to acknowledge financial support provided by DBT via inclusion of Reference/ Grant number, Name of the Department (i.e. DBT) and the duration of the financial support including the dates in acknowledgement section of publications/patents/technology transfer documents vide notification no. DBT/PCAH/Gen/01 dated 7th June 2012.

11. It is obligatory to assess/observe the biosafety compliance for rDNA activities to be performed by institutions and investigators for the proposals submitted to DBT for financial support as per the notification vide no. BT/BS/17/459/2011-PID dated 26th September 2012.

12. As per Rule 236(1) of GFR 2017, Audit of accounts- The account of Grantee Institutions or Organizations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG(DPC) Act 1971 and internal audit by the Principal Account Office of the Ministry or Department, whenever the institution or Organization is called upon to do so.

13. In case the whole or a part of the amount of the grant-in-aid is being refunded, as an interest at the rate of ten per cent per annum thereon shall be recovered.

14. UC/SE must show all the heads as per the sanction order.

15. As per Ministry of Finance OM. No. C-13015(34)/MF CGA/PFMS/Misc/2014-15/2095-2127 dated 03.03.2015 all transaction involving cash component has to be made through Public Financial Management System (PFMS) w.e. 01.04.2015 to each beneficiaries.

16. Failure to comply with the terms and conditions of this sanction order will entail full refund with interest in terms of Rule 231 (2) of GFR 2017.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

17. This issues under the powers delegated to this Department and with the concurrence of IFD vide their **Dy. No. 102/IFD/SAN/338/2019-2020 dated 07.05.2019.**

18. This sanction order has been noted at **Serial No. 04** in the Register of Grants maintained in division.

(Amit P. Parikh)
Scientist 'E'

To,

The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003

Copy to:

1. The Principal Director of Audit (Scientific Departments), IP Estate, AGCR Building, New Delhi-110002
2. Cash Section, DBT (2 copies)
3. IFD, DBT
4. The Registrar, KLE Academy of Higher Education and Research, Belagavi, Karnataka
5. Dr. Shivaprasad S Goudar, KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka
6. Dr. Mrutyunjaya Bellad, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
7. Dr. Mrityunjay Metgud, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
8. Dr. Sangappa Dhaded, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
9. Dr. Manjunath Somannavar, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
10. Dr. Umesh Charantimath, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
11. Sanction Folder

(Amit P. Parikh)
Scientist 'E'

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

KLE Academy of Higher Education and Research
Women's and Children's Health Research Unit
J N Medical College
COST REIMBURSABLE RESEARCH SUBCONTRACT
"Low birthweight Infant Feeding Exploration (LIFE)"

This contract Agreement for **"Low birthweight Infant Feeding Exploration (LIFE)"** in Karnataka Sub-site, India hereafter referred to as the **"LIFE"** is entered into in order to specify the terms and conditions under which the KLE Academy of Higher Education and Research, Women's and Children's Health Research Unit, J N Medical College, (hereinafter referred to as "JNMC") and JJM Medical College Davangere, Karnataka (hereinafter referred to as "JJMMC") will participate in the conduct of a project supported by the Harvard School of Public Health, USA (HSPH) (hereinafter referred to as "Sponsor").

General Information:
Title: Research Subcontract in between Jawaharlal Nehru Medical College, Belgaum and JJM Medical
College, Davangere, Karnataka for the **"LIFE"**

Award Title: This Hospital & Community based Observational Cohort Contract (the "Contract"), effective as of Nov 1, 2018
(the "Effective Date") is by and between President and Fellows of Harvard College and Jawaharlal Nehru Medical College located at Belgaum 590010 in Karnataka, India ("JNMC"), represented by its employee Dr Shivaprasad Goudar, MD (the "Principal Investigator").

Prime Award : Between President and Fellows of Harvard College & Bill & Melinda Gates Foundation: Agreement. Investment ID – OPP1192260
Sub Award: Between President and Fellows of Harvard College & JNMC Sub Award - Agreement. 5111046-261426

Principal Investigator Name: Dr Shivaprasad S Goudar (JNMC)
Site Co- Principal Investigator Name: Dr G Guruprasad (JJMMC)

WHEREAS, JNMC and Sponsor entered into an agreement on 15 June 2017, attached hereto (Attachment A) and incorporated by this reference, wherein JNMC was to provide certain services to Sponsor for the **"LIFE"**

WHEREAS, JNMC and JJMMC wish to enter into a subcontract wherein JJMMC will provide certain services to JNMC in JNMC's performance of the contract with Harvard School of Public Health, USA (HSPH);

WHEREAS, JJMMC agrees to abide by all of the terms and conditions of the Sponsor-Harvard School of Public Health, USA (HSPH) agreement;

WHEREAS, the Agreement is for work approved by Sponsor as a portion of the statement of work shown in Attachment A & Attachment B;

NOW, THEREFORE, the parties agree that the foregoing statements of fact are true and correct and are

incorporated herein by this reference. In consideration of the covenants and conditions contained in this Agreement ("the Agreement"), and other good and valuable consideration, the adequacy and receipt of which are acknowledged, JNMC and JJMMC agree as follows:

Definitions:

1. "JNMC" means the Jawaharlal Nehru Medical College, which has its principal office in Belgaum, India.
2. "HSPH" means Harvard School of Public Health, USA.
3. "JJMMC" means Jagadguru Jayadeva Murugarajendra Medical College, Davanegere, Karnataka which has its principal office in Davangere, Karnataka, India, and which pursuant to the Protocol, agrees to provide data entry, data management, and data quality control services and to dedicate an employee to serve as a Co-Investigator (as defined below) for the Hospital-based Trial. JJMMC has legal Administrative and operative control of the below listed Hospital.
    1. Bapuji Child Health Institute Davangere (herein after referred to as BCHID as the context Permits)
    2. Chigateri General Hospital Davangere (herein after referred to as CGHD as the context Permits- (Attachment D-)
    3. Women's and Children's Hospital Davangere (herein after referred to as W&CHD as the Context permits (Attachment D)

Article I. Scope of Work provided in Attachment A

JJMMC, as a Sub-Contractor of JNMC, agrees to provide all the necessary qualified personnel, equipment, materials (except as otherwise may be provided herein), and facilities to perform the work as described in its proposal, which by this reference is incorporated into this Agreement , Attachment A & Attachment B.

JJMMC will facilitate the implementation of research protocol (Attachment B) at

1. Bapuji Child Health Institute Davangere (herein after referred to as BCHID as the context Permits)
2. Chigateri General Hospital Davangere (herein after referred to as CGHD as the context Permits- (Attachment D-)
3. Women's and Children's Hospital Davangere (herein after referred to as W&CHD as the Context permits) (Attachment D)

JJMMC will provide designated places for storage and administration of the research protocol at the above said facilities. JJMMC will ensure that the study documents will be stored at the above designated facilities under lock and key.

Article II. Period of Performance

The period of this Agreement shall be from Jan 1, 2018 to June 30, 2020 unless extended by written amendment to this Agreement.

Article III. Estimated Cost

JNMC agrees to pay JJMMC an amount not to exceed Rs. 2,061,554 for the work described in Article I which includes 15% Indirect costs payable to JJMMC.

ATTESTED

JNMC will provide equipment to JJMMC for the implementation of the project costing up to Rs. 11,19,825/-

JNMC will also reimburse JJMMC towards Screening, reimbursements of data captions, cost of IDI, FGD & transcription of IDI and FGDs will be directly paid by JNMC .
JJMMC will extend credit facility to the site investigators towards expenditures by investigations and sample collection as requested by the Site Principal Investigator until reimbursement is processed by JNMC. JNMC will process all Invoices within 45 days of receipt of the Invoices.

JJMMC's budget is incorporated into this Agreement as Attachment C. The allowance of costs will be determined in accordance with JNMC's methods of determining costs under its grants and contracts with the Sponsor, and with the Sponsor's policies applicable to research projects as in effect on the beginning date of the budget period of this Agreement. Where JJMMC is normally required by these current policies to seek prior approval for actions from the Sponsor, JJMMC shall direct its request to the Administrative Representative of JNMC

JNMC will pay remuneration to the faculty and consultants from JJMMC working on this project directly. Indirect costs associated with these remunerations will be transferred to the administrative account of JJMMC on a monthly basis (Attachment C) in adherence to the Scope of Work (SOW). JJMMC will submit audited statement of expenses to JNMC every six months. Required supporting documentation, to be submitted with invoices, is clearly detailed and incorporated into this agreement as Attachment A.

The Project funds will be transferred to JJMMC

INSTITUTION ACCOUNT DETAILS

Name of Institution	: JJM Medical College, Davangere
Address of Institution	: JJM, Medical College, Campus, Davangere Karnataka
Bank Account Holder's Name/Beneficiary Name	: Dean and Principal
Bank Account No. (For NEFT/RTGS/E-Payment)	:
Type of Account (Current A/c)	:
Bank IFSC Code	:
Bank MICR Code	:
Bank Code	:

JJMMC is to submit monthly invoice to JNMC on a cost reimbursable basis. Required supporting documentation, to be submitted with invoices, is clearly detailed and incorporated into this Agreement as Attachment A

ATTESTED

The indirect costs provide for institutional costs that benefit and support research. These costs are included in budget build research capacity at JJMMC. These funds may be utilized for the following Activities.

- Use, maintenance and upgrading of building space, utilities and libraries;
- central technical support of labs, offices, core and other facilities;
- management and administration of research, finances, regulatory requirements and research compliance (i.e. research ethics, biohazards certification, animal care etc.);
- hazardous waste disposal;
- radiation and occupational safety and security; and
- liability insurance.

The utilization of funds received as indirect costs towards strengthening of research capacity at JJMMC will be in consultation between the site Principal Investigator and Administration of JJMMC.

ArticleIV. Authorized Representatives

The authorized representatives of JNMC and JJMMC for technical and administrative matters shall be:

JJM Medical College, Davangere,Karnataka

Technical Representative:
Dr Gowdar Guruprasad,
Administrative Representative:
Dr S B Murugesh
Dean & Principal

J N Medical College, Belgaum

Technical Representative:
Dr Shivaprasad S Goudar
Administrative Representative:
Dr.N S Mahantshetti
Principal

Article V. Reports

As stated in Article VII Section C paragraph 3, JJMMC must submit its most recent audit report to the JNMC Audit Representative.

Quarterly financial reports are required by JJMMC if it is not required under Article VII, entitled "Additional General Provisions", Section C paragraph 3, to submit its most recent audit report. The financial reports must be submitted to the JNMC Audit Representative.

Final Progress Report - A Final Progress Report shall be submitted to the JNMC Technical Representative within sixty (60) days of the close of the final project period for inclusion in the Principal Investigator's Final Progress Report.

ATTESTED

Article VI. General Provisions

The work to be performed under this Agreement is being supported by the Sponsor under Agreement Attachment B. Therefore, wherever applicable, the rules and regulations governing the award to JNMC are by this reference hereby incorporated into this Agreement, including, but not limited to, provisions governing care and treatment of laboratory animals, civil rights and equal employment opportunity, protection of human subjects, patents and inventions, publications and rights in data.

Article VII. Additional General Provisions

The following general provisions shall apply to this Agreement:

A. Allowable Costs

Allowable costs shall be determined by JNMC in accordance with cost principles generally accepted by, or required to be used by, similar institutions or organizations, that are in effect as of the effective date of this Agreement.

B. Billing

JNMC shall reimburse the JJMMC 's payment within forty (40) days after receipt of an acceptable invoice and after inspection and acceptance of the research deliverables provided in accordance with the terms and conditions of this Agreement.

JJMMC agrees that bills and invoices for fees or other compensation for services or expenses shall cite the Title: **"LIFE"**

The performance of JNMC of any of its obligations under this Agreement shall be subject to and contingent upon the availability of funds, and the obligation of funds by the prime funding agency (Sponsor), or otherwise lawfully expendable for the purposes of this Agreement for the current and future periods. JNMC shall give notice to JJMMC of the non-availability of such funds when JNMC has knowledge of such fact. Upon receipt of such notice by JJMMC, JJMMC shall be entitled to payment only for those services performed and expenses incurred prior to the date notice is received.

If this Agreement includes travel expenditures, any such expenditure, including reimbursement, must comply with University or JNMC rules and itemized in detail.

JJMMC shall submit invoices based on the payment schedule specified in Article III, Cost. A final invoice must be received within 30 days after the budget period end date. Please forward all invoices to the following address:

Dr Shivaprasad S Goudar
Principal Investigator
Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research
J N Medical College
Nehru Nagar,
Belgaum, 590010
sgoudar@jnmc.edu

ATTESTED

C. Audit

JJMMC shall maintain and have available for audit and inspection all administrative and financial documents, and all other records, pertinent to the financial costs allocated to this agreement for a period of three years following the termination date except that, if an audit is initiated before the expiration of the three year period, the records shall be retained until audit findings have been resolved. The above records are subject to inspection and audit by JNMC, its designated representatives or representatives of Sponsor at all reasonable times during the life of the grant and for three years thereafter.

Any costs reimbursed by JNMC which are subsequently found to be disallowed under audit shall be refunded to JNMC by JJMMC. JJMMC agrees to comply with the requirements. In cases of non-compliance with Indian laws and regulations, JJMMC will also provide copies of responses to auditor's reports and a plan for corrective action. All records and reports prepared in accordance with the requirements shall be available for inspection by JNMC, its designated representatives or representatives of Sponsor at all reasonable times during the life of the grant and for three years thereafter.

If JJMMC is required to perform an Audit, JJMMC must provide JNMC with a copy of its most recent audit report.

D. Equipment

JNMC and JJMMC agree that if JJMMC purchases permanent equipment under this Agreement, title to such equipment will vest in the JNMC under the same conditions as apply under JNMC's grant with the Sponsor and that JNMC shall have the same rights to require transfer of equipment as the Sponsor has.

E. Indemnification

Each party hereby assumes any and all risk of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees and agents thereof. JJMMC will assure that persons subcontracting with or otherwise acting or engaged to act at the instance of JJMMC in furtherance of JJMMC fulfilling its obligations under this Agreement will assume such risk with respect to the willful or negligent acts or omissions of their personnel. JJMMC shall provide professional liability coverage for its employees discharging services as per the provisions of this contract and accident insurance coverage for all equipment/material procured for conducting the trial as specified in Attachment B.

F. Amendments

Any amendments, including renewals, alterations or modifications to the Agreement must be signed by the signatories to this Agreement.

G. Governance

The validity, construction and effect of this Agreement shall be governed by the prevailing laws. In the event either party is required to obtain from any governmental authority any permit, license or authorization as a prerequisite to perform its obligations under this Agreement, the cost shall be borne by the party required to obtain such permit, license or authorization.

JJMMC shall allow access to all documents, papers, letters or other material subject to the provisions of this Contract, and made or received by JJMMC in conjunction with this Agreement to JNMC or its

ATTESTED

Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

representatives, the regulatory authorities or the representatives of the sponsor as specified in Attachment B. Refusal by JJMMC to allow such access shall be grounds for cancellation of this Agreement by JNMC.

JJMMC may not, without the advance written approval of JNMC, assign any right or delegate any duties under this Agreement nor may it transfer, pledge, surrender or otherwise encumber or dispose of its interest in any portion of this Agreement

It is understood and agreed that nothing contained in this Agreement is intended, or should be construed, as creating or establishing the relationship of partners between the parties, or as constituting JJMMC as the agent or representative of JNMC for any purpose in any manner whatsoever. JJMMC is not authorized to bind JNMC to any contracts or other obligations. JJMMC shall not expressly or impliedly represent to any party that HSPH and JNMC are partners or that JNMC is the agent or representative of Harvard School of Public Health, USA (HSPH) for any purpose or in any manner whatsoever.

H. Termination

JNMC or JJMMC may terminate this Agreement upon thirty (30) days written notice to the other party. However, in the event that the Sponsor terminates the Agreement with JNMC prior to the period end date, this Agreement will be immediately terminated. In the event of termination JNMC will pay for costs incurred and non-cancelable commitments through the date of termination, contingent upon JNMC having received sufficient funds from Sponsor. JJMMC will furnish all necessary reports of research completed or in progress through the date of termination.

I. Publications

Any publications resulting from this Agreement shall be governed by the policies laid out in Attachment B.

J. Arbitration

If any dispute arises in between JNMC and JJMMC the same should be referred to Chancellor, KLE University and Chairman, KLE Society, Belgaum and Honorable Chairman, BEA Davangere, Karnataka and the decision of the Arbitrators shall be final and the same shall be binding on the both the parties.

JJMMC certifies that to the best of its knowledge and belief that it and its principals will abide by the payment Standard Operating Procedures in Attachment A and Attachment B.

ATTESTED

Prof. Dr. V.A. KOTTI
R...
KLE Academy of Higher Education
and Research, BELAGAVI

This Contract includes the following Appendices (incorporated herein):

Attachment A:

Attachment B:

Attachment C:

IN WITNESS WHEREOF, JNMC and JJMMC have executed and delivered this Contract by and through their duly authorized representatives below

Jawaharlal Medical College (JNMC)

By: _____

Name: Dr N S Mahantshetti

Title: Principal

Date: 01/02/2019
DD /MM /YYYY

JJM Medical College, Davangere, Karnataka (JJMMC)

By: _____

Name: Dr. S B Murugesh

Title: Dean & Principal

Date: 31/01/2019
DD /MM /YYYY

Principal Investigator

By: _____

Name: Dr Shivaprasad S Goudar

Title: Professor Department of PHYSIOLOGY

Date: 01/02/2019
DD /MM /YYYY

By: _____

Name: Gowdar Guruprasad

Title: Professor and Head, Neonatology

Date: 31/01/2019
DD /MM /YYYY

ATTESTED

Bapuji Educational Association®

J.J.M. MEDICAL COLLEGE

(Recognised by the Medical Council of India, New Delhi, Vide No. Mci-34(1)87-Med./12101 dt. 6-8-1987)

DAVANGERE-577 004, KARNATAKA, INDIA.

Ref-No: JJMMC/5289/2018-19 Date: 03.01.2019

To,

Dr.Shamanur Shivashankarappa MLA
Chairman,
Bapuji Educational Association,
Davangere

Respected sir,

Sub: Research Study programme **"Low-birth weight Infant Feeding Exploration** (LIFE) project" in Collaboration with JNMC Belagavi.

With Respect to the above subject, we would like to bring to your kind notice that collaborative study **"Low-birth weight Infant Feeding Exploration (LIFE) project"** With the financial funding support from 'BILL AND MELINDA GATES FOUNDATION', is planned to undertake in our both esteemed medical colleges JJMMC & SSIMS.

The study Period is around 2 years starting from Jan 2019 to Dec 2020. We request you to kindly approve this proposal. For the conduct of this study, there will be no financial expenditure from our side.

It is one of the prestigious research study that our institute is under taking, and it is headed by Dr.G.Guruprasad Prof & HOD Department Of Neonatology.

We are glad to inform that Sri S.S.Mallikarjun, Chairman, Bapuji Child Health Institute & Research Centre, has approved for implementation of the project after thorough discussion.

We seek your kind Permission and Guidance for the same.

Kindly oblige and do the needful.

Thanking You

Yours Faithfully

Dr.G.Guruprasad
Co- Principal Investigator
Prof & HOD Dept of Neonatology
JJMMC Davangere

Dr.S.B.Murugesh
Principal
JJMMC
Davangere

ATTESTED

RESEARCH SUB AGREEMENT

This Research Sub Agreement is made and executed on 15th October of 2019 by and between

KLE Academy of Higher Education & Research
Women's and Children's Health Research Unit
Jawaharlal Nehru Medical College,
Nehru Nagar, Belagavi.
Represented by the Principal
Dr N. S. Mahantshetti

Hereinafter referred to as "JNMC"

AND

S Nijalingappa Medical College
Bagalkot,
Represented by its Principal
Dr Ashok Mallapur

(Hereinafter referred to as "SNMC")

Eunice Kennedy Shriver National Institutes of Child Health
and Human Development
Global Network for Women's and Children's Health Research

(Hereinafter referred to as "Sponsor").

Title : "The A-PLUS Study on Infection"

Award Title: This Community-based Trial Contract (the "Contract"), effective as of October 15, 2019 (the "Effective Date") is by and between TJU / GLOBAL NETWORK and Jawaharlal Nehru Medical College located at Belgaum 590010 in Karnataka, India ("JNMC"), represented by its employee Dr Shivaprasad Goudar, MD (the "Principal Investigator").

Prime Award: PTE Federal Award No - 2UG1HD076457-07,
Sub-award No: - 080-70000-S22902

Principal Investigator Name : Dr Shivaprasad S Goudar (JNMC)
Facility Director Name : Dr Ashalata Mallapur (SNMC)

Preamble:

WHEREAS, JNMC and Sponsor entered into an agreement on 15 October 2019, attached hereto (Attachment A) and incorporated by this reference, wherein JNMC was to provide certain services to Sponsor for **"Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labor (in low- and middle-income countries):** titled as **The A-PLUS Study on**

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

KAHER * BELAGAVI * J.N. MEDICAL COLLEGE

J.N.Medical College, BELAGAVI

WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT - JNMC

Infection" in Bagalkot sub-site. India.

FURTHER SNMC will participate in the conduct of the project and agrees to abide by all the terms and conditions of the Sponsor. Pursuant to the Protocol, SNMC agrees to provide data entry, data management, and data quality control services and to dedicate an employee to serve as a Co-Investigator for the Community-based Trial.

WHEREAS, the Agreement is for work approved by Sponsor as a portion of the statement of work shown in Attachment A & Attachment B;

NOW, THEREFORE, the parties agree that the foregoing statements of fact are true and correct and are incorporated herein by this reference. In consideration of the covenants and conditions contained in this Agreement ("the Agreement"), and other good and valuable consideration, the adequacy and receipt of which are acknowledged, JNMC and SNMC agree as follows:

Definitions:

4. "JNMC" means the Jawaharlal Nehru Medical College, which has its principal office in Belgaum, India
5. TJU / GLOBAL NETWORK
6. "SNMC" means S N Medical College, which has its principal office in Bagalkot, India,

Article I. Scope of Work

SNMC, as a Sub-Contractor of JNMC, agrees to provide all the necessary qualified personnel, equipment, materials (except as otherwise may be provided herein), and facilities to perform the work as described in its proposal, which by this reference is incorporated into this Agreement , Attachment A & Attachment B.

JNMC shall provide the upgraded equipment and material to SNMC for performance of the said project as and when required.

Article II. Period of Performance

The period of this Agreement shall be from November 15, 2019 to May 31, 2020 unless extended by written amendment to this Agreement.

Article III. Consideration

SNMC shall deploy its qualified personnel for accomplishment of the said project. The salaries and other expenses shall be credited directly to the personal account of the employees. SNMC shall provide the details of bank accounts, salary statement and invoices for any incidental expenses incurred by SNMC. JNMC shall reimburse the incidental expenses unconnected with the Prime Award, if any, incurred by SNMC, through cheque/DD drawn in favour of "The Principal, SNMC. SNMC is not entitled to 8% of Indirects' received by the Sponsor, due to amendments to the FCRA Regulations.

ATTESTED

J N Medical College, BELAGAVI

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Article IV. Authorized Representatives

The authorized representatives of JNMC and SNMC for technical and administrative matters shall be:

S N Medical College, Bagalkot	J N Medical College, Belgaum
Technical Representative:	***Technical Representative:***
Dr Ashalata Mallapur,	Dr Shivaprasad S Goudar
Administrative Representative:	***Administrative Representative:***
Dr Ashok Mallapur	Dr.N S Mahantshetti
Dean/Principal	Principal

Article V. Reports

Final Progress Report - A Final Progress Report shall be submitted to the JNMC Technical Representative within sixty (60) days of the close of the final project period for inclusion in the Principal Investigator's Final Progress Report.

Article VI. General Provisions

The work to be performed under this Agreement is being supported by the Sponsor under Agreement Attachment B. Therefore, wherever applicable, the rules and regulations governing the award to JNMC are by this reference hereby incorporated into this Agreement, including, but not limited to, provisions governing care and treatment of laboratory animals, civil rights and equal employment opportunity, protection of human subjects, patents and inventions , publications and rights in data.

Article VII. Additional General Provisions

The following general provisions shall apply to this Agreement:

A. Allowable Costs

Allowable costs shall be determined by JNMC in accordance with cost principles generally accepted by, or required to be used by, similar institutions or organizations, that are in effect as of the effective date of this Agreement.

B. Billing

JNMC shall reimburse the SNMC 's payment within forty (40) days after receipt of

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

an acceptable invoice provided in accordance with the terms and conditions of this Agreement.

The performance of JNMC of any of its obligations under this Agreement shall be subject to and contingent upon the availability of funds, and the obligation of funds by the prime funding agency (Sponsor), or otherwise lawfully expendable for the purposes of this Agreement for the current and future periods. JNMC shall give notice to SNMC of the non-availability of such funds when JNMC has knowledge of such fact. Upon receipt of such notice by SNMC, the employees of SNMC shall be entitled to payment only for those services performed and expenses incurred prior to the date notice is received.

C. Equipment

JNMC and SNMC agree that if SNMC purchases permanent equipment under this Agreement, title to such equipment will vest in the JNMC under the same conditions as apply under JNMC's grant with the Sponsor and that JNMC shall have the same rights to require transfer of equipment as the Sponsor has.

Further if JNMC provides any equipment to SNMC for implementation of the present agreement, the title to such equipment shall vest in SNMC exclusively and SNMC shall not transfer such equipment to JNMC upon accomplishment of the project.

D. Indemnification

Each party hereby assumes any and all risk of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees and agents thereof. SNMC will assure that persons subcontracting with or otherwise acting or engaged to act at the instance of SNMC in furtherance of SNMC fulfilling its obligations under this Agreement will assume such risk with respect to the willful or negligent acts or omissions of their personnel. SNMC shall provide professional liability coverage for its employees discharging services as per the provisions of this contract and accident insurance coverage for all equipment/material procured for conducting the trial as specified in Attachment B.

E. Amendments

Any amendments, including renewals, alterations or modifications to the Agreement must be signed by the signatories to this Agreement.

F. Governance

The validity, construction and effect of this Agreement shall be governed by the prevailing laws. In the event either party is required to obtain from any governmental authority any permit, license or authorization as a prerequisite to perform its obligations under this Agreement, the cost shall be borne by the party required to obtain such permit, license or authorization.

SNMC shall allow access to all documents, papers, letters or other material subject

ATTESTED

J N Medical College, BELAGAVI

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

to the provisions of this Contract, and made or received by SNMC in conjunction with this Agreement to JNMC or its representatives, the regulatory authorities or the representatives of the sponsor as specified in Attachment B. Refusal by SNMC to allow such access shall be grounds for cancellation of this Agreement by JNMC.

SNMC may not, without the advance written approval of JNMC, assign any right or delegate any duties under this Agreement nor may it transfer, pledge, surrender or otherwise encumber or dispose of its interest in any portion of this Agreement

It is understood and agreed that nothing contained in this Agreement is intended, or should be construed, as creating or establishing the relationship of partners between the parties, or as constituting SNMC as the agent or representative of JNMC for any purpose in any manner whatsoever. SNMC is not authorized to bind JNMC to any contracts or other obligations. SNMC shall not expressly or impliedly represent to any party that University of British Columbia and JNMC are partners or that JNMC is the agent or representative of TJU / GLOBAL NETWORK for any purpose or in any manner whatsoever.

G. Termination

JNMC or SNMC may terminate this Agreement upon thirty (30) days written notice to the other party. However, in the event that the Sponsor terminates the Agreement with JNMC prior to the period end date, this Agreement will be immediately terminated. In the event of termination JNMC will pay for costs incurred and non-cancelable commitments through the date of termination, contingent upon JNMC having received sufficient funds from Sponsor. SNMC will furnish all necessary reports of research completed or in progress through the date of termination.

H. Publications

Any publications resulting from this Agreement shall be governed by the policies laid out in Attachment B.

II. Arbitration

If any dispute arises in between JNMC and SNMC the same should be referred to Chancellor, KLE University and Chairman, KLE Society, Belgaum and The Chairman,Basaveshwar Veerashaiva Vidyavardhaka Sangha, Bagalkot and the decision of the Arbitrators shall be final and the same shall be binding on the both the parties.

SNMC certifies that to the best of its knowledge and belief that it and its principals will abide by the payment Standard Operating Procedures in Attachment A and Attachment B

This Contract includes the following Appendices (incorporated herein):
Attachment A: Prime Award Title no: 2UG1HD076457-07 for A-PLUS Study
Attachment B: Protocol Version 22 May 2024, Number:1.4.1
Attachment C: Budget Sheet for 07 months Version 1.4.1

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

J.N. MEDICAL COLLEGE * KAHER * BELAGAVI

J.N Medical College, BELAGAVI
WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT - JNMC

IN WITNESS WHEREOF, JNMC and SNMC have executed and delivered this agreement by and through their duly authorized representatives below

Jawaharlal Medical College (JNMC)

By:_____

Name: Dr N S Mahantshetti

Title: Principal

Date: 15/10/2019

S N Medical College (SNMC)

By:_____

Name: Dr Ashok Mallapur

Title: Dean/Principal

Date:

Principal Investigator

By:_____

Name: Dr Shivaprasad S Goudar

Title: Professor Department of PHYSIOLOGY

Date: 15/10/2019

By:_____

Name: Dr Ashalata Mallapur

Title: Professor and Head, Department of OBGYN

Date:

ATTESTED

[illegible] KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*	
WHO Reference	2018/850957-0
Purchase Order	202089996
Unit Reference	RHR/MPA

DR.Shivaprasad Goudar
PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

TECHNICAL SERVICES AGREEMENT (TSA)

Re: Umbiflow International Study - A-ID: A65924

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 4,597,150.00 (Four Million Five Hundred Ninety-Seven Thousand One Hundred Fifty), for conducting the above-mentioned work. We also enclosed four attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

On behalf of the World Health Organization, we thank you for your collaboration.

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: Umbiflow International Study - A-ID: A65924

Veuillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de INR 4,597,150.00 (Four Million Five Hundred Ninety-Seven Thousand One Hundred Fifty), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver four pièces jointes mentionnées dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signee du Bon de Commande (complet)

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsible technique Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

Au nom de l'Organisation Mondiale de la Santé, nous vous remercions de votre collaboration.

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

31/10/2018

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/850957-0
Purchase Order	202089996
Unit Reference	RHR/MPA

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
INSTITUTION:

PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM
(JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
PRINCIPAL INVESTIGATOR
Karnataka
India

Principal Investigator: DR.Shivaprasad Goudar
Telephone:
Fax:
Email/Courriel: sgoudar@jnmc.edu

The Amount of/*Un Montant de*: INR 4,597,150.00 (Four Million Five Hundred Ninety-Seven Thousand One Hundred Fifty)
in respect of/*en vue de:* Umbiflow International Study - A-ID: A65924

For the period financed by this Agreement From/*De* : 08-OCT-2018
Période du projet financée par le présent accord To/*A* : 30-SEP-2019

Summary of work/ *Description sommaire des travaux:*

1 Description of work under this Agreement/ *Description des travaux faisant l'objet du présent accord:*

Please see attached detailed Protocol and budget.

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities). The Institute will provide all facilities, equipment and personnel not covered by this Agreement.
Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc. à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ *Dispositions financiers:*

1. Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Countersigned contract	08-OCT-2018	100.00	4,597,150.00
2	Technical report	31-JUL-2019	0.00	0.00
3	Final financial report	30-SEP-2019	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 *seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.*

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de cet accord:*

Annex	File Description/Description de fichier
1	2018/850957 | Contractual - Statement of Work |
2	2018/850957 | Contractual - Budget Breakdown |
3	2018/850957 | Contractual - Terms of Reference | Protocol
4	2018/850957 | Contractual - Statement of Work | CTRI Registration Certificate

In the event that the terms of the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les termes apparaissant sur les annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.*

General
The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.
All necessary arrangements to comply with national regulations

Généralités
Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de

ATTESTED

Prof. Dr. V.A.KOTHIWALE
REGISTRAR
KLE Academy of Higher Education and Research, BELAGAVI

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World Health Organization

Global Procurement and Logistics
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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Olufemi Taiwo Oladapo
Medical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

Ian ASKEW
Director
HQ/RHR - Reproductive Health and Research

Authorized Signatory:
Signataire autorisé:

Mr Francisco E.V. Cardenas
Director
Global Service Centre
(WHO/GMG/GSC)

Francisco E.V. Cardenas
Director
HQ/GSC Global Service Centre
01-OCT-2018

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature : .....
DR.Shivaprasad Goudar 3/10/2018

ON BEHALF OF THE INSTITUTION/ *POUR L'INSTITUTION*

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : Dr. N. S. Mahantashetti
Division : Principal, JN Medical College, Belagavi
Date : .....

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution./*Un responsable de l'institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.*

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services. The purpose of such support is to assist an Institution to undertake, for WHO, investigations on a particular problem or other work which has been agreed upon by the Institution and WHO.

1. INSTITUTION AND PRINCIPAL INVESTIGATOR
1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement
1.2 The Institution is required to notify WHO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities covered by this Agreement. Under such circumstances WHO has the right to:
(a) terminate this Agreement; or
(b) agree to continue the project under a new Principal Investigator proposed by the Institution and approved by WHO.

2. FINANCIAL ARRANGEMENTS
2.1 Payments shall be made into the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein. If after the submission of the final financial report referred to in paragraph 4.4 below, there remains an unused balance of funds with the Institution, this balance shall be due to WHO. In the event of this Agreement being terminated under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds. The funds provided under this Agreement shall be expended only in accordance with its terms
2.2 The funds transferred to the Institution under this Agreement may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to a staff member of WHO.
2.3 Unless otherwise provided in this Agreement, the funds transferred to the Institution hereunder may not be used to cover;
(a) normal administrative and overhead expenses of the Institution;
(b) cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution;
(c) cost of construction of new buildings or alterations and modifications of existing buildings and premises; or
(d) salary support of the Principal Investigator

3. EQUIPMENT AND SUPPLIES; PROCUREMENT
3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment and supplies acquired under this Agreement shall become the property of the Institution. The Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment and supplies acquired under this Agreement.
3.2 Notwithstanding subparagraph 3.1 above, the Institution shall transfer ownership of any equipment and supplies acquired under this Agreement to WHO, if so requested by WHO upon termination or expiry of this Agreement. In such cases the Institution shall dispatch the equipment and supplies to any destination chosen by WHO, the cost of which will be borne by WHO.
3.3 To the extent the Institution needs to purchase any goods and/or services in connection with its performance of this Agreement, the Institution shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

4. REPORTS; AUDIT
The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions.
4.1 Technical reports shall be prepared by the Principal Investigator and forwarded through and countersigned by the authorized official of the Institution or his authorized representative. Each annual report shall summarize the results of the project and give in sufficient detail its positive and negative findings so that the value of the work can be assessed.
4.2 Financial reports shall be forwarded after being jointly certified by the Institution's chief financial officer and the Principal Investigator, using form WHO 782. The reports must show the use of the funds provided by WHO compared with the original budget expenditure pattern agreed between the Institution and WHO.
4.3 WHO may request a financial and/or operational review or audit of the project and related activities, to be conducted by WHO and/or parties authorized by WHO, and the Institution undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this Agreement, or within five years of completion of the work hereunder. The Institution shall make available, without restriction, to WHO and/or parties authorized by WHO:
(a) the Institution's books, records and systems (including all relevant financial and operational information) relating to the project and related activities; and
(b) reasonable access to the Institution's premises and personnel.
In order to facilitate financial reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project and related activities. The Institution shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.
WHO may request the Institution to provide complementary information about the project and related activities that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Institution and related to the Project and/or related activities
4.4 The final technical and financial reports must be submitted within 90 days after the expiry of this Agreement

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES
The relationship of the Institution to WHO shall be that of an independent

Such funds may be used only to support investigations where
(a) the rights and welfare of the subjects involved in the research are adequately protected,
(b) freely given informed consent has been obtained,
(c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution and
(d) any special national requirements have been met
8.2 Regulatory Requirements
It is the responsibility of the Institution and the Principal Investigator to comply with the relevant national regulations pertaining to research involving human subjects
8.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 8.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and Principal Investigator undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this Agreement

9. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS
The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

10. RESEARCH SAFETY
It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the research to be carried out under this Agreement. If the supported research involves the use of dangerous biological agents, the Institution shall establish and implement an appropriate safety plan.

11. COMPLIANCE WITH WHO POLICIES
By entering into this Agreement, the Institution and Principal Investigator acknowledge that they have read, and hereby accept and agree to comply with, the WHO Policies (as defined below). In connection with the foregoing, the Institution and Principal Investigator shall take appropriate measures to prevent any violations of the standards of conduct (as described in the WHO Policies) by employees of the Institution and any other persons engaged by the Institution and/or Principal Investigator to perform any services under this Agreement. Without limiting the foregoing, the Institution and Principal Investigator shall each promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the Institution and/or Principal Investigator become aware. For purposes of this Agreement, the term "WHO Policies" means collectively:
(a) the WHO Code of Ethics and Professional Conduct;
(b) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response;
(c) the WHO Code of Conduct for Responsible Research;
(d) the WHO Policy on Whistleblowing and Protection Against Retaliation; and
(e) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

12. ZERO TOLERANCE FOR SEXUAL EXPLOITATION AND ABUSE
WHO has zero tolerance towards sexual exploitation and abuse in this regard, and without limiting any other provisions contained herein,
- the Institution warrants that it will:
(a) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform any services under this Agreement; and
(b) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Institution becomes aware; and
- The Principal Investigator warrants that he/she will:
(a) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and
(b) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Principal Investigator becomes aware.

13. TOBACCO- AND ARMS-RELATED DISCLOSURE
The Institution is required to disclose relationships it may have with the tobacco and/or arms industry through completion of the WHO Tobacco / Arms Disclosure Statement. The Institution undertakes not to permit work under this Agreement to commence until WHO has assessed the disclosed information and confirmed to the Institution in writing that the work can commence.

14. ANTI-TERRORISM AND UN SANCTIONS; FRAUD AND CORRUPTION
14.1 The Institution and Principal Investigator warrant for the entire duration of this Agreement that:
(a) they are not and will not be involved in, or associated with, any person or entity associated with terrorism as designated by any UN Security Council sanctions regime; that they will not make any payment or provide any other support to any such person or entity; and that they will not enter into any employment or

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Prof. Dr. V.A.KOTHIWALE
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and Research, BELAGAVI

World Health Organization

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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO. The Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement. No liability shall attach to WHO, its advisors, agents or employees.

6. USE OF RESULTS, EXPLOITATION OF RIGHTS.

6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The Institution shall provide WHO with the results, in the form of relevant know how and other information, and to the extent feasible, tangible products.

6.2 The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:

(a) the general availability of the products of creative activity;

(b) the availability of those products to the public health sector on preferential terms, particularly in developing countries;

(c) the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.

6.3 The rights referred to in paragraph. 6.2 shall belong to the Institution, or to the Principal Investigator if the Institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the Institution and WHO.

7. PUBLICATIONS

7.1 Subject to any proprietary rights of WHO and/or third parties collaborating with WHO, the work supported by WHO under this Agreement may be published by the Institution and/or the Principal Investigator. In order to avoid prejudicing proprietary rights, the Institution or the Principal Investigator shall transmit to WHO for its review the material intended to be published at least 60 working days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of any objection by WHO within that 60 working day period concerning prejudice to its proprietary rights, the publication may proceed.

7.2 Any publication by the Institution or the Principal Investigator of the work supported by WHO under this Agreement shall be published in accordance with the WHO policy on open access, which is available at the following link: http://www.who.int/about/policy/en/

7.3 In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation received financial support from WHO. Two off-prints or copies of each publication shall be sent to WHO unless another number is stipulated. WHO funds may not be used for publication costs unless specifically authorized.

8. RESEARCH INVOLVING HUMAN SUBJECTS

8.1 Ethical Aspects

It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments.

subcontracting relationship with any such person or entity; and

(b) They shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.

14.2 The Institution and Principal Investigator shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.

14.3 Any funds used by the Institution and/or Principal Investigator for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

15. BREACH OF ESSENTIAL TERMS

The Institution and Principal Investigator acknowledge and agree that each of the provisions in Sections 11, 12, 13 and 14 hereof constitutes an essential term of this Agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

(a) terminate this Agreement and/or any other contract concluded by WHO with the Institution and/or Principal Investigator, immediately upon written notice to them, without any liability for termination charges or any other liability of any kind; and/or

(b) exclude the Institution and/or Principal Investigator from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any breach of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

16. PUBLICITY; USE OF WHO NAME AND EMBLEM

16.1 The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of an advertising or promotional nature, including but not limited to any statements or materials issued for commercial purposes or with a view to financial benefit.

16.2 Without WHO's prior written approval, the Institution and/or the Principal Investigator shall not, in any statement or material of an advertising or promotional nature, refer to this Agreement or to the Institution's and/or Principal Investigator's relationship with WHO, or otherwise use the name (or any abbreviation thereof) or emblem of the World Health Organization.

17. PUBLICATION OF AGREEMENT

Subject to considerations of confidentiality, WHO may acknowledge the existence of this Agreement to the public and publish and/or otherwise publicly disclose the name of the Institution and/or Principal Investigator, the Institution's country of incorporation, general information with respect to the work supported under this Agreement, and this Agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this Agreement.

18. SURVIVING PROVISIONS

These provisions of this Agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

19. SETTLEMENT OF DISPUTES

Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

20. PRIVILEGES AND IMMUNITIES

Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

31/10/2018

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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Unit Reference	RHR/MPA

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'institution et l'OMS

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord

1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

(a) soit résilier le présent Accord;

(b) soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.4, il apparaît que l'Institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas de résiliation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense

2.3 Sauf dispositions contraires du présent Accord, les fonds versés à l'Institution en vertu des présentes ne peuvent être utilisés pour couvrir:

(a) les dépenses administratives et les frais généraux normaux de l'Institution;

(b) le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;

(c) le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants; ou

(d) le versement d'un complément de traitement au Chercheur principal

3. MATERIEL ET FOURNITURES; ACHAT

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel et toutes fournitures obtenus en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation, de la maintenance et de l'entretien de tout matériel et de toutes fournitures acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord, les droits de propriété afférents à tout matériel et à toutes fournitures acquis au titre dudit Accord. L'Institution expédiera alors ce matériel et ces fournitures vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

3.3 Dans la mesure où l'Institution doit acheter des biens et/ou des services dans le cadre de l'exécution du présent Accord, elle devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

4. RAPPORTS ; AUDIT

L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes :

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l'autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont avaient convenu l'Institution et l'OMS

4.3 L'OMS peut demander qu'un examen ou un audit de type financier et opérationnel du projet et des activités y afférentes, soit effectué par l'OMS et/ou par des parties autorisées par l'OMS, et l'Institution s'engage à faciliter cet examen ou cet audit. Cet examen ou cet audit peut être effectué à tout moment pendant la mise en œuvre du projet au titre du présent Accord, ou dans les cinq ans suivant son achèvement. L'Institution permettra à l'OMS et/ou aux parties autorisées par celle-ci, sans restriction

(a) de consulter ses livres, archives et systèmes (y compris l'ensemble des informations financières et opérationnelles pertinentes) relatifs au projet et aux activités y afférentes; et

(b) d'avoir un accès raisonnable à ses locaux et à son personnel.

Afin de faciliter l'établissement de rapports financiers et la réalisation d'un audit financier, l'Institution tiendra des comptes et des registres exacts et systématiques concernant le projet et les activités y afférentes. L'Institution fournira des

(a) les droits et le bien-être des sujets impliqués sont protégés comme il convient,

(b) le consentement libre et éclairé des intéressés a été obtenu;

(c) un groupe d'experts indépendants désignés par l'Institution ont posé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et

(d) toute exigence particulière de la réglementation nationale a été satisfaite.

8.2 Dispositions réglementaires

Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

8.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des dispositions appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 8.1. Ces dispositions comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord

9. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'Institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes généralement admis destinés à assurer un traitement humain des animaux et à leur épargner toute souffrance inutile.

10. SECURITE DES RECHERCHES

Il incombe à l'Institution d'établir et d'appliquer des politiques et pratiques visant à préserver et garantir la sécurité de ses employés, celle du public et de de l'environnement pendant le déroulement des recherches qui seront effectuées au titre du présent Accord. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'Institution établira et appliquera un plan de sécurité approprié.

11. RESPECT DES POLITIQUES DE L'OMS

En signant le présent Accord, l'Institution et le Chercheur principal reconnaissent avoir lu les politiques de l'OMS (telles que définies ci-après) et, par les présentes, acceptent ces politiques et conviennent de s'y conformer. En lien avec ce qui précède, l'Institution et le Chercheur principal prendront les mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les politiques de l'OMS, par les employés de l'Institution ou toute autre personne que l'Institution et/ou le Chercheur principal aura engagée en vue de fournir un quelconque service au titre du présent Accord. Sans limiter la portée de ce qui précède, l'Institution et le Chercheur principal signaleront immédiatement à l'OMS, conformément aux dispositions des politiques de l'OMS applicables, toute violation réelle ou présumée dont ils ont connaissance concernant toute politique de l'OMS. Aux fins du présent Accord, l'expression « politiques de l'OMS » désigne, collectivement :

(a) le Code d'éthique et de déontologie de l'OMS,

(b) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels,

(c) le Code de conduite pour une recherche responsable,

(d) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles et

e) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants : http://www.who.int/about/finances-accountability/procurement/en/ (pour ce qui est du Code de conduite des fournisseurs des Nations Unies) et http://www.who.int/about/ethics/en/ (pour ce qui est des autres politiques de l'OMS).

12. TOLERANCE ZERO POUR L'EXPLOITATION ET LES ABUS SEXUELS

L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. A cet égard, et sans limiter la portée de toute autre disposition du présent Accord

- l'Institution garantit:

(a) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle en vue de fournir un quelconque service au titre du présent Accord ; et

(b) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique, et

- le Chercheur principal garantit:

(a) qu'il n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, et

(b) qu'il signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont il a connaissance, conformément aux dispositions de la Politique

13. DECLARATION RELATIVE A L'INDUSTRIE DU TABAC/DE L'ARMEMENT

L'Institution est tenue de déclarer ses éventuelles relations avec l'industrie du tabac et de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Elle s'engage à ne pas autoriser le commencement des travaux tant que l'OMS n'a pas évalué les informations

Annexe 6

31/10/2018

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
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World Health Organization

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TECHNICAL SERVICES AGREEMENT
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explications satisfaisantes en réponse à toutes les questions découlant de l'audit et des droits d'accès susmentionnés.
L'OMS pourra demander à l'Institution de lui communiquer des informations complémentaires concernant le projet et les activités y afférentes qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'un audit (interne ou externe) effectué par l'Institution et relatif au projet et/ou aux activités y afférentes.
4.4 Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES
L'Institution agira à l'égard de l'OMS en tant qu'entrepreneur indépendant; ses employés ne pourront se prévaloir de la qualité de membres du personnel de l'OMS. L'Institution sera seule responsable de la façon dont s'exécute le projet et, partant, assumera l'entière responsabilité de tout dommage résultant de recherches ou d'autres services techniques visés par le présent Accord. Aucune responsabilité ne pourra incomber à l'OMS, ses conseillers, agents ou employés.

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS
6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut du consentement de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres informations pertinents et, dans la mesure du possible, lui fournira des produits concrets.
6.2 L'exploitation industrielle ou commerciale de tout droit de propriété intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité.
(a) mise à la disposition générale de tous les produits de l'activité créatrice;
(b) leur mise à la disposition auprès du secteur de la santé publique, à des conditions préférentielles, en particulier dans les pays en développement;
(c) octroi à chaque partie d'avantages additionnels, y compris sous formes de royalties, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.
6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l'autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exerceront aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

7. PUBLICATIONS
7.1 Sous réserve des droits de propriété de l'OMS et/ou de tiers qui collaborent avec elle, les travaux financés par l'OMS au titre du présent Accord peuvent être publiés par l'Institution et/ou le Chercheur principal. Afin d'éviter de porter atteinte à des droits de propriété, l'Institution ou le Chercheur principal transmettra à l'OMS, pour examen, le document qu'il est prévu de publier, au moins 60 jours ouvrables avant qu'une proposition de publication ne soit présentée à un quelconque éditeur, maison d'édition, arbitre scientifique ou organisateur d'une réunion. Si l'OMS ne formule aucune objection pendant ces 60 jours ouvrables concernant une violation de ses droits de propriété, la publication peut avoir lieu.
7.2 Toute publication, par l'Institution ou le Chercheur principal, des travaux financés par l'OMS au titre du présent Accord se fera conformément à la politique de l'OMS en matière de libre accès, qui peut être consultée à l'adresse suivante : http://www.who.int/about/policy/fr/.
7.3 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirages de chaque publication seront envoyés à l'OMS. Sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

8. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS
8.1 Aspects éthiques
Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et le bien-être de ces derniers soient protégés conformément au code éthique ou à la législation appropriés du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies :
communiquées et confirmé par écrit à l'Institution que ces travaux peuvent commencer.

14. ANTI-TERRORISME ET SANCTIONS DE L'ONU; FRAUDE ET CORRUPTION
14.1 L'Institution et le Chercheur principal garantissent, pour toute la durée du présent Accord :
(a) qu'ils ne sont ni ne seront impliqués à l'égard de, ni associés à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité des Nations Unies a désignée comme étant associée au terrorisme, qu'ils ne feront aucun paiement à, ou ne soutiendront d'aucune autre manière, à une telle personne ou entité, et qu'ils ne concluront aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité, et
(b) qu'ils ne prendront part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord.
14.2 L'Institution et le Chercheur principal prendront toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord.
14.3 Toute somme que l'Institution et/ou le Chercheur principal utiliseraient pour promouvoir une quelconque activité terroriste ou une quelconque pratique illégale, de corruption, de fraude, de collusion ou de coercition sera remboursée à l'OMS sans délai.

15. VIOLATION DE CLAUSES ESSENTIELLES
L'Institution et le Chercheur principal reconnaissent et acceptent que chacune des dispositions des sections 11, 12, 13 et 14 des présentes constitue une clause essentielle du présent Accord et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :
(a) de résilier immédiatement le présent Accord, et/ou tout autre contrat conclu par l'OMS avec l'Institution et/ou le Chercheur principal, moyennant une notification écrite adressée à ceux-ci, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou
(b) d'exclure l'Institution et/ou le Chercheur principal de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.
L'OMS sera en droit de rapporter toute violation de ces dispositions à ses organes directeurs, aux autres organismes des Nations Unies et/ou aux donateurs.

16. PUBLICITE ; UTILISATION DU NOM ET DE L'EMBLEME DE L'OMS
16.1 L'Institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel, y compris, sans s'y limiter, ceux qui sont diffusés à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet ou les produits ou procédés en découlant.
16.2 Ni l'Institution ni le Chercheur principal n'auront le droit, dans une déclaration ou support à caractère publicitaire ou promotionnel, de faire référence au présent Accord ou à leur relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

17. PUBLICATION DE L'ACCORD
Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence du présent Accord et de publier, et/ou rendre public d'une autre manière, le nom de l'Institution et/ou du Chercheur principal, le pays d'enregistrement de l'Institution, des informations générales concernant les travaux financés au titre des présentes et la valeur du présent Accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent Accord.

18. DISPOSITIONS RESTANT EN VIGUEUR APRES LA FIN DE L'ACCORD
Les dispositions du présent Accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée de l'Accord continueront de s'appliquer.

19. REGLEMENT DES DIFFERENDS
Toute question concernant l'interprétation ou l'application du présent Accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent Accord qui n'aurait pu être résolu à l'amiable, fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, seront déterminées selon le Règlement d'arbitrage de la Chambre de commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

20. PRIVILEGES ET IMMUNITES
Aucun des termes du présent Accord ni rien qui s'y rapporte ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

8/10/2018

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

COVERING LETTER:
LETTRE D'ACCOMPAGNEMENT

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WHO Reference/ *Référence OMS*

WHO Reference	2018/850957-0
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Unit Reference	RHR/MPA

DR.Shivaprasad Goudar
PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

TECHNICAL SERVICES AGREEMENT (TSA)

Re: Umbiflow International Study - A-ID: A65924

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 4,597,150.00 (Four Million Five Hundred Ninety-Seven Thousand One Hundred Fifty), for conducting the above-mentioned work. We also enclosed four attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

On behalf of the World Health Organization, we thank you for your collaboration.

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: Umbiflow International Study - A-ID: A65924

Veuillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de INR 4,597,150.00 (Four Million Five Hundred Ninety-Seven Thousand One Hundred Fifty), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver four pièces jointes mentionnées dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signee du Bon de Commande (complet)

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsible technique Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

Au nom de l'Organisation Mondiale de la Santé, nous vous remercions de votre collaboration.

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

31/10/2018

ATTESTED

Prof. Dr V.A KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
INSTITUTION:

PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM
(JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
PRINCIPAL INVESTIGATOR
Karnataka
India

Principal Investigator: DR.Shivaprasad Goudar
Telephone:
Fax:
Email/Courriel: sgoudar@jnmc.edu

The Amount of/*Un Montant de*: INR 4,597,150.00 (Four Million Five Hundred Ninety-Seven Thousand One Hundred Fifty)
in respect of/*en vue de*: Umbiflow International Study - A-ID: A65924

For the period financed by this Agreement — From/*De* : 08-OCT-2018
***Période du projet** financée par le présent accord* — To/*A* : 30-SEP-2019

Summary of work/ *Description sommaire des travaux:*

1. Description of work under this Agreement/ *Description des travaux faisant l'objet du présent accord:*

Please see attached detailed Protocol and budget.

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities)
The Institute will provide all facilities, equipment and personnel not covered by this Agreement.
Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc. à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord

Financial Arrangements/ *Dispositions financiers:*

1. Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Countersigned contract	08-OCT-2018	100.00	4,597,150.00
2	Technical report	31-JUL-2019	0.00	0.00
3	Final financial report	30-SEP-2019	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 *seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.*

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de cet accord:*

Annex	File Description/Description de fichier
1	2018/850957 | Contractual - Statement of Work |
2	2018/850957 | Contractual - Budget Breakdown |
3	2018/850957 | Contractual - Terms of Reference | Protocol
4	2018/850957 | Contractual - Statement of Work | CTRI Registration Certificate

In the event that the terms of the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les termes apparaissant sur les annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.*

General
The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.
All necessary arrangements to comply with national regulations

Généralités
Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de

ATTESTED
Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

World Health Organization

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WHO Reference/ *Référence OMS*

WHO Reference	2018/850957-0
Purchase Order	202089996
Unit Reference	RHR/MPA

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relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Olufemi Taiwo Oladapo
Medical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

Ian ASKEW
Director
HQ/RHR - Reproductive Health and Research

Authorized Signatory:
Signataire autorisé:

Mr Francisco E.V. Cardenas
Director
Global Service Centre
(WHO/GMG/GSC)

Francisco E.V. Cardenas
Director
HQ/GSC Global Service Centre
01-OCT-2018

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature : .....
DR.Shivaprasad Goudar 3/10/2018

ON BEHALF OF THE INSTITUTION/ *POUR L'INSTITUTION*

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : Dr. N.S. Mahantashetti
Division : Principal, JN Medical College, Belagavi
Date : 5/10/18

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution./*Un responsable de l'Institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.*

ATTESTED

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World Health Organization

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GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services. The purpose of such support is to assist an Institution to undertake, for WHO, investigations on a particular problem or other work which has been agreed upon by the Institution and WHO.

1. INSTITUTION AND PRINCIPAL INVESTIGATOR
1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement.
1.2 The Institution is required to notify WHO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities covered by this Agreement. Under such circumstances WHO has the right to:
(a) terminate this Agreement; or
(b) agree to continue the project under a new Principal Investigator proposed by the Institution and approved by WHO.

2. FINANCIAL ARRANGEMENTS
2.1 Payments shall be made into the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein. If, after the submission of the final financial report referred to in paragraph 4.4 below, there remains an unused balance of funds with the Institution, this balance shall be due to WHO. In the event of this Agreement being terminated under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds. The funds provided under this Agreement shall be expended only in accordance with its terms.
2.2 The funds transferred to the Institution under this Agreement may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to a staff member of WHO.
2.3 Unless otherwise provided in this Agreement, the funds transferred to the Institution hereunder may not be used to cover:
(a) normal administrative and overhead expenses of the Institution;
(b) cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution;
(c) cost of construction of new buildings or alterations and modifications of existing buildings and premises; or
(d) salary support of the Principal Investigator.

3. EQUIPMENT AND SUPPLIES; PROCUREMENT
3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment and supplies acquired under this Agreement shall become the property of the Institution. The Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment and supplies acquired under this Agreement.
3.2 Notwithstanding subparagraph 3.1 above, the Institution shall transfer ownership of any equipment and supplies acquired under this Agreement to WHO, if so requested by WHO upon termination or expiry of this Agreement. In such cases the Institution shall dispatch the equipment and supplies to any destination chosen by WHO, the cost of which will be borne by WHO.
3.3 To the extent the Institution needs to purchase any goods and/or services in connection with its performance of this Agreement, the Institution shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

4. REPORTS; AUDIT
The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions.
4.1 Technical reports shall be prepared by the Principal Investigator and forwarded through and countersigned by the authorized official of the Institution or his authorized representative. Each annual report shall summarize the results of the project and give in sufficient detail its positive and negative findings so that the value of the work can be assessed.
4.2 Financial reports shall be forwarded after being jointly certified by the Institution's chief financial officer and the Principal Investigator, using form WHO 782. The reports must show the use of the funds provided by WHO compared with the original budget expenditure pattern agreed between the Institution and WHO.
4.3 WHO may request a financial and/or operational review or audit of the project and related activities, to be conducted by WHO and/or parties authorized by WHO, and the Institution undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this Agreement, or within five years of completion of the work hereunder. The Institution shall make available, without restriction, to WHO and/or parties authorized by WHO:
(a) the Institution's books, records and systems (including all relevant financial and operational information) relating to the project and related activities, and
(b) reasonable access to the Institution's premises and personnel.
In order to facilitate financial reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project and related activities. The Institution shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.
4.4 WHO may request the Institution to provide complementary information about the project and related activities that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Institution and related to the Project and/or related activities.
4.4 The final technical and financial reports must be submitted within 90 days after the expiry of this Agreement.

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES
The relationship of the Institution to WHO shall be that of an independent

Such funds may be used only to support investigations where
(a) the rights and welfare of the subjects involved in the research are adequately protected;
(b) freely given informed consent has been obtained;
(c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution; and
(d) any special national requirements have been met.
8.2 Regulatory Requirements
It is the responsibility of the Institution and the Principal Investigator to comply with the relevant national regulations pertaining to research involving human subjects.
8.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 8.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and Principal Investigator undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this Agreement.

9. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS
The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

10. RESEARCH SAFETY
It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the research to be carried out under this Agreement. If the supported research involves the use of dangerous biological agents, the Institution shall establish and implement an appropriate safety plan.

11. COMPLIANCE WITH WHO POLICIES
By entering into this Agreement, the Institution and Principal Investigator acknowledge that they have read, and hereby accept and agree to comply with, the WHO Policies (as defined below). In connection with the foregoing, the Institution and Principal Investigator shall take appropriate measures to prevent any violations of the standards of conduct (as described in the WHO Policies) by employees of the Institution and any other persons engaged by the Institution and/or Principal Investigator to perform any services under this Agreement. Without limiting the foregoing, the Institution and Principal Investigator shall each promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the Institution and/or Principal Investigator become aware. For purposes of this Agreement, the term "WHO Policies" means collectively:
(a) the WHO Code of Ethics and Professional Conduct;
(b) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response;
(c) the WHO Code of Conduct for Responsible Research;
(d) the WHO Policy on Whistleblowing and Protection Against Retaliation, and
(e) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

12. ZERO TOLERANCE FOR SEXUAL EXPLOITATION AND ABUSE
WHO has zero tolerance towards sexual exploitation and abuse in this regard, and without limiting any other provisions contained herein,
- the Institution warrants that it will
(a) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform any services under this Agreement; and
(b) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Institution becomes aware; and
- The Principal Investigator warrants that he/she will
(a) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and
(b) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Principal Investigator becomes aware.

13. TOBACCO- AND ARMS-RELATED DISCLOSURE
The Institution is required to disclose relationships it may have with the tobacco and/or arms industry through completion of the WHO Tobacco / Arms Disclosure Statement. The Institution undertakes not to permit work under this Agreement to commence until WHO has assessed the disclosed information and confirmed to the Institution in writing that the work can commence.

14. ANTI-TERRORISM AND UN SANCTIONS; FRAUD AND CORRUPTION
14.1 The Institution and Principal Investigator warrant for the entire duration of this Agreement that:
(a) they are not and will not be involved in, or associated with, any person or entity associated with terrorism as designated by any UN Security Council sanctions regime; that they will not make any payment or provide any other support to any such person or entity; and that they will not enter into any employment or

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contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO. The Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement. No liability shall attach to WHO, its advisers, agents or employees

6. USE OF RESULTS, EXPLOITATION OF RIGHTS.

6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The Institution shall provide WHO with the results, in the form of relevant know how and other information, and to the extent feasible, tangible products.

6.2 The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:

(a) the general availability of the products of creative activity;

(b) the availability of those products to the public health sector on preferential terms, particularly in developing countries;

(c) the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.

6.3 The rights referred to in paragraph. 6.2 shall belong to the Institution, or to the Principal Investigator if the Institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the Institution and WHO.

7. PUBLICATIONS

7.1 Subject to any proprietary rights of WHO and/or third parties collaborating with WHO, the work supported by WHO under this Agreement may be published by the Institution and/or the Principal Investigator. In order to avoid prejudicing proprietary rights, the Institution or the Principal Investigator shall transmit to WHO for its review the material intended to be published at least 60 working days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of any objection by WHO within that 60 working day period concerning prejudice to its proprietary rights, the publication may proceed.

7.2 Any publication by the Institution or the Principal Investigator of the work supported by WHO under this Agreement shall be published in accordance with the WHO policy on open access, which is available at the following link: http://www.who.int/about/policy/en/.

7.3 In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation received financial support from WHO. Two off-prints or copies of each publication shall be sent to WHO unless another number is stipulated. WHO funds may not be used for publication costs unless specifically authorized.

8. RESEARCH INVOLVING HUMAN SUBJECTS

8.1 Ethical Aspects

It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments.

subcontracting relationship with any such person or entity; and

(b) They shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.

14.2 The Institution and Principal Investigator shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.

14.3 Any funds used by the Institution and/or Principal Investigator for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay

15. BREACH OF ESSENTIAL TERMS

The Institution and Principal Investigator acknowledge and agree that each of the provisions in Sections 11, 12, 13 and 14 hereof constitutes an essential term of this Agreement, and that in case of breach of any of those provisions, WHO may, in its sole discretion, decide to:

(a) terminate this Agreement and/or any other contract concluded by WHO with the Institution and/or Principal Investigator, immediately upon written notice to them, without any liability for termination charges or any other liability of any kind; and/or

(b) exclude the Institution and/or Principal Investigator from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any breach of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

16. PUBLICITY; USE OF WHO NAME AND EMBLEM

16.1 The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of an advertising or promotional nature, including but not limited to any statements or materials issued for commercial purposes or with a view to financial benefit.

16.2 Without WHO's prior written approval, the Institution and/or the Principal Investigator shall not, in any statement or material of an advertising or promotional nature, refer to this Agreement or to the Institution's and/or Principal Investigator's relationship with WHO, or otherwise use the name (or any abbreviation thereof) or emblem of the World Health Organization.

17. PUBLICATION OF AGREEMENT

Subject to considerations of confidentiality, WHO may acknowledge the existence of this Agreement to the public and publish and/or otherwise publicly disclose the name of the Institution and/or Principal Investigator, the Institution's country of incorporation, general information with respect to the work supported under this Agreement, and this Agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this Agreement.

18. SURVIVING PROVISIONS

Those provisions of this Agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

19. SETTLEMENT OF DISPUTES

Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

20. PRIVILEGES AND IMMUNITIES

Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction

31/10/2018

ATTESTED

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CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'institution et l'OMS

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

(a) soit résilier le présent Accord;

(b) soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.6, il apparaît que l'Institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas de résiliation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.

2.3 Sauf dispositions contraires du présent Accord, les fonds versés à l'Institution en vertu des présentes ne pouvent être utilisés pour couvrir:

(a) les dépenses administratives et les frais généraux normaux de l'Institution;

(b) le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;

(c) le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants; ou

(d) le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES; ACHAT

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel et toutes fournitures obtenus en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation, de la maintenance et de l'entretien de tout matériel et de toutes fournitures acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord, les droits de propriété afférents à tout matériel et à toutes fournitures acquis au titre dudit Accord. L'Institution expédiera alors ce matériel et ces fournitures vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

3.3 Dans la mesure où l'Institution doit acheter des biens et/ou des services dans le cadre de l'exécution du présent Accord, elle devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

4. RAPPORTS ; AUDIT

L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l'autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont avaient convenu l'Institution et l'OMS.

4.3 L'OMS peut demander qu'un examen ou un audit de type financier et opérationnel du projet et des activités y afférentes, soit effectué par l'OMS et/ou par des parties autorisées par l'OMS, et l'Institution s'engage à faciliter cet examen ou cet audit. Cet examen ou cet audit peut être effectué à tout moment pendant la mise en œuvre du projet au titre du présent Accord, ou dans les cinq ans suivant son achèvement. L'Institution permettra à l'OMS et/ou aux parties autorisées par celle-ci, sans restriction

(a) de consulter ses livres, archives et systèmes (y compris l'ensemble des informations financières et opérationnelles pertinentes) relatifs au projet et aux activités y afférentes; et

(b) d'avoir un accès raisonnable à ses locaux et à son personnel.

Afin de faciliter l'établissement de rapports financiers et la réalisation d'un audit financier, l'Institution tiendra des comptes et des registres exacts et systématiques concernant le projet et les activités y afférentes. L'Institution fournira des

(a) les droits et le bien-être des sujets impliqués sont protégés comme il convient,

(b) le consentement libre et éclairé des intéressés a été obtenu;

(c) un groupe d'experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et

(d) toute exigence particulière de la réglementation nationale a été satisfaite.

8.2 Dispositions réglementaires

Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

8.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des dispositions appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 8.1. Ces dispositions comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord

9. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'Institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes généralement admis destinés à assurer un traitement humain des animaux et à leur épargner toute souffrance inutile.

10. SECURITE DES RECHERCHES

Il incombe à l'Institution d'établir et d'appliquer des politiques et pratiques visant à préserver et garantir la sécurité de ses employés, celle du public et de de l'environnement pendant le déroulement des recherches qui seront effectuées au titre du présent Accord. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'Institution établira et appliquera un plan de sécurité approprié.

11. RESPECT DES POLITIQUES DE L'OMS

En signant le présent Accord, l'Institution et le Chercheur principal reconnaissent avoir lu les politiques de l'OMS (telles que définies ci-après) et, par les présentes, acceptent ces politiques et conviennent de s'y conformer. En lien avec ce qui précède, l'Institution et le Chercheur principal prendront les mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les politiques de l'OMS, par les employés de l'Institution ou toute autre personne que l'Institution et/ou le Chercheur principal aura engagée en vue de fournir un quelconque service au titre du présent Accord. Sans limiter la portée de ce qui précède, l'Institution et le Chercheur principal signaleront immédiatement à l'OMS, conformément aux dispositions des politiques de l'OMS applicables, toute violation réelle ou présumée dont ils ont connaissance concernant toute politique de l'OMS. Aux fins du présent Accord, l'expression « politiques de l'OMS » désigne, collectivement ,

(a) le Code d'éthique et de déontologie de l'OMS,

(b) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels,

(c) le Code de conduite pour une recherche responsable,

(d) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles et

e) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants ; http://www.who.int/about/finances-accountability/procurement/en/ (pour ce qui est du Code de conduite des fournisseurs des Nations Unies) et http://www.who.int/about/ethics/en/ (pour ce qui est des autres politiques de l'OMS).

12. TOLERANCE ZERO POUR L'EXPLOITATION ET LES ABUS SEXUELS

L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. A cet égard, et sans limiter la portée de toute autre disposition du présent Accord

- l'Institution garantit:

(a) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle en vue de fournir un quelconque service au titre du présent Accord , et

(b) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et

- le Chercheur principal garantit:

(a) qu'il n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et a la lutte contre l'exploitation et les abus sexuels, et

(b) qu'il signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont il a connaissance, conformément aux dispositions de la Politique.

13. DECLARATION RELATIVE A L'INDUSTRIE DU TABAC/DE L'ARMEMENT

L'Institution confirme et déclarer ses éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Elle s'engage a ne pas autoriser le commencement des travaux tant que l'OMS n'a pas évalué les informations

31/10/2018

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Registrar
KLE Academy of Higher Education and Research, BELAGAVI

World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/850957-0
Purchase Order	202089996
Unit Reference	RHR/MPA

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

explications satisfaisantes en réponse à toutes les questions découlant de l'audit et des droits d'accès susmentionnés.
L'OMS pourra demander à l'Institution de lui communiquer des informations complémentaires concernant le projet et les activités y afférentes qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'un audit (interne ou externe) effectué par l'Institution et relatif au projet et/ou aux activités y afférentes.
4.4 Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES
L'Institution agira à l'égard de l'OMS en tant qu'entrepreneur indépendant; ses employés ne pourront se prévaloir de la qualité de membres du personnel de l'OMS. L'Institution sera seule responsable de la façon dont s'exécute le projet et, partant, assumera l'entière responsabilité de tout dommage résultant de recherches ou d'autres services techniques visés par le présent Accord. Aucune responsabilité ne pourra incomber à l'OMS, ses conseillers, agents ou employés.

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS
6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut du consentement de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales ou, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres informations pertinents et, dans la mesure du possible, lui fournira des produits concrets.
6.2 L'exploitation industrielle ou commerciale de tout droit de propriété intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:
(a) mise à la disposition générale de tous les produits de l'activité créatrice;
(b) leur mise à la disposition auprès du secteur de la santé publique, à des conditions préférentielles, en particulier dans les pays en développement;
(c) octroi à chaque partie d'avantages additionnels, y compris sous formes de royalties, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.
6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l'autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

7. PUBLICATIONS
7.1 Sous réserve des droits de propriété de l'OMS et/ou de tiers qui collaborent avec elle, les travaux financés par l'OMS au titre du présent Accord peuvent être publiés par l'Institution et/ou le Chercheur principal. Afin d'éviter de porter atteinte à des droits de propriété, l'Institution ou le Chercheur principal transmettra à l'OMS, pour examen, le document qu'il est prévu de publier, au moins 60 jours ouvrables avant qu'une proposition de publication ne soit présentée à un quelconque éditeur, maison d'édition, artiste scientifique ou organisateur d'une réunion. Si l'OMS ne formule aucune objection pendant ces 60 jours ouvrables concernant une violation de ses droits de propriété, la publication peut avoir lieu.
7.2 Toute publication, par l'Institution ou le Chercheur principal, des travaux financés par l'OMS au titre du présent Accord se fera conformément à la politique de l'OMS en matière de libre accès, qui peut être consultée à l'adresse suivante : http://www.who.int/about/policy/fr/ .
7.3 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirages de chaque publication seront envoyés à l'OMS. Sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

8. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS
8.1 Aspects éthiques
Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et le bien-être de ces derniers soient protégés conformément au code éthique ou à la législation appropriés du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies:
communiquées et confirmé par écrit à l'Institution que ces travaux peuvent commencer.

14. ANTI-TERRORISME ET SANCTIONS DE L'ONU; FRAUDE ET CORRUPTION
14.1 L'Institution et le Chercheur principal garantissent, pour toute la durée du présent Accord :
(a) qu'ils ne sont ni ne seront impliqués à l'égard de, ni associés à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité des Nations Unies a désignée comme étant associée au terrorisme, qu'ils ne feront aucun paiement à, ou ne soutiendront d'aucune autre manière, à une telle personne ou entité, et qu'ils ne concluront aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité, et
(b) qu'ils ne prendront part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord,
14.2 L'Institution et le Chercheur principal prendront toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord,
14.3 Toute somme que l'Institution et/ou le Chercheur principal utiliseraient pour promouvoir une quelconque activité terroriste ou une quelconque pratique illégale, de corruption, de fraude, de collusion ou de coercition sera remboursée à l'OMS sans délai.

15. VIOLATION DE CLAUSES ESSENTIELLES
L'Institution et le Chercheur principal reconnaissent et acceptent que chacune des dispositions des sections 11, 12, 13 et 14 des présentes constitue une clause essentielle du présent Accord et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :
(a) de résilier immédiatement le présent Accord, et/ou tout autre contrat conclu par l'OMS avec l'Institution et/ou le Chercheur principal, moyennant une notification écrite adressée à ceux-ci, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou
(b) d'exclure l'Institution et/ou le Chercheur principal de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.
L'OMS sera en droit de rapporter toute violation de ces dispositions à ses organes directeurs, aux autres organismes des Nations Unies et/ou aux donateurs.

16. PUBLICITE ; UTILISATION DU NOM ET DE L'EMBLEME DE L'OMS
16.1 L'Institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel, y compris, sans s'y limiter, ceux qui sont diffusés à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet ou les produits ou procédés en découlant.
16.2 Ni l'Institution ni le Chercheur principal n'auront le droit, dans une déclaration ou support à caractère publicitaire ou promotionnel, de faire référence au présent Accord ou à leur relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

17. PUBLICATION DE L'ACCORD
Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence du présent Accord et de publier, et/ou rendre public d'une autre manière, le nom de l'Institution et/ou du Chercheur principal, le pays d'enregistrement de l'Institution, des informations générales concernant les travaux financés au titre des présentes et la valeur du présent Accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent Accord.

18. DISPOSITIONS RESTANT EN VIGUEUR APRES LA FIN DE L'ACCORD
Les dispositions du présent Accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée de l'Accord continueront de s'appliquer.

19. REGLEMENT DES DIFFERENDS
Toute question concernant l'interprétation ou l'application du présent Accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent Accord qui n'aurait pu être résolu à l'amiable, fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, seront déterminées selon le Règlement d'arbitrage de la Chambre de commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

20. PRIVILEGES ET IMMUNITES
Aucun des termes du présent Accord ni rien qui s'y rapporte ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

8/10/2018

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

INDIA NON JUDICIAL

Government of Karnataka

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डॉ. एस. एल. होटी वैज्ञानिक-जी
Dr. S. L. Hoti Scientist-G
आयुर्वेदसंशोधन-राष्ट्रीय पारंपरिक चिकित्साविज्ञान संस्थान
ICMR - National Institute of Traditional Medicine
नेहरू नगर, बेलगावी-५९००१० Nehru Nagar, Belagavi-59

ATTESTED

Prof. Dr. V. A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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MEMORANDUM OF UNDERSTANDING

BETWEEN

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES (CCRAS)

AND

ICMR-NATIONAL INSTITUTE OF TRADITIONAL MEDICINE, BELAGAVI

AND

KLE UNIVERSITY, BELAGAVI

This memorandum of understanding (MoU) entered into and executed on 09th August 2017 Between **Central Council for Research in Ayurvedic Sciences** (hereinafter referred to as **"CCRAS"),** a society registered under the Societies Registration Act 1860, having its office at 61-65, Opp. 'D' Block, Institutional Area, Janakpuri, New Delhi of the First part.

AND

ICMR-National Institute of Traditional Medicine, Belagavi (hereinafter referred to as **"ICMR-NITM"),** formerly known as Regional Medical Research Centre (RMRC) established by Indian Council of Medical Research (ICMR) having its office at Nehru Nagar, National Highway No.4, Belagavi-590010 of the Second part.

AND

KLE University, Belagavi (hereinafter referred to as **"KLEU"),** having its office at JNMC Campus, Nehru Nagar, Belagavi-590010 of the Third part.

1. OBJECTIVE OF THE MOU

To carry out the collaborative research project entitled **"Evaluation of Add on Efficacy & Safety of An Ayurvedic Formulation in the Management of Dengue Fever & Prevention of its complications – A Double Blind Clinical Study"** as per the terms and conditions and guidelines of CCRAS Research Policy.

2. PROPOSED MODES OF COLLABORATION

CCRAS, ICMR-NITM and **KLEU** propose to collaborate through:

2.1 Undertaking the research project entitled **"Evaluation of Add on Efficacy & Safety of An Ayurvedic Formulation in the Management of Dengue Fever & Prevention of its complications – A Double Blind Clinical Study"** with duration of **Two years.**

2.2 Research work will be carried out at ICMR-NITM, KLE University's, JN Medical College, Belagavi, and Shri BMK Ayurveda Mahavidyalaya, Belagavi premises as appropriate wherein Dr. S. L. Hoti, Scientist G, Dr. V. A. Kothiwale, Vice principal, Dept. of General Medicine and Dr. B.S. Prasad Principal will be the investigators respectively.

3. CCRAS, ICMR-NITM and **KLEU** are interested in collaborating with each other to facilitate the execution of this project with sharing of following responsibilities:

23/8/ J.N. MEDICAL COLLEGE BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

डॉ. एस. एल. होटी वैज्ञानिक-जी
Dr. S. L. Hoti Scientist-G
आयुर्वेदिक औषध-राष्ट्रीय पारम्परिक चिकित्साविज्ञान संस्थान
ICMR - National Institute of Traditional Medicine
नेहरू नगर, बेलगावी-५९००१० Nehru Nagar, Belagavi-590010

3.1 Responsibilities of CCRAS

3.1.1 CCRAS agrees for collaborative research project entitled "Evaluation of Add on Efficacy & Safety of An Ayurvedic Formulation in the Management of Dengue Fever & Prevention of its complications – A Double Blind Clinical Study" with ICMR-NITM and KLEU.

3.1.2 Standardized Coded Ayurvedic drug and the matching placebo (for administration along with Standard care) will be provided by **CCRAS** for the clinical trial.

3.1.3 Entire funding for the proposed project will be extended by **CCRAS** while the execution of the project will be done at ICMR-NITM, KLE University's JN Medical College and Shri BMK Ayurveda Mahavidyalaya, Belagavi as per the guidelines of CCRAS Research Policy.

3.1.4 The funds will be released in the name of the Director of the Institution, **ICMR-NITM, Belagavi.**

3.1.5 A Monitoring Committee (consisting of three/four members) nominated by DG, CCRAS /his representative (the funding agency) and DG, ICMR-will monitor the project from time to time.

3.2 Responsibilities of ICMR-NITM

3.2.1 **ICMR-NITM** will conduct aforesaid research project as approved by CCRAS as per the protocol and as per the guidelines of CCRAS Research Policy. It will be responsible for the virological and immunological components of the project.

3.2.2 ICMR-NITM will release the funds to Principal(s) KLEU's JN Medical College and Shri BMK Ayurveda Mahavidyalaya, Belagavi for execution of the project as per the sanction order.

3.2.3 The ethical clearance (from Institutional Ethics Committee) of this project will be obtained by the participating centres as appropriate for conducting the research work.

3.2.4 The Investigators will be responsible for timely completion of the project with submission of detailed technical report, fund utilization certificate along with the statement of expenditure.

3.2.5 **ICMR-NITM** will support the Monitoring Committee for monitoring of the project from time to time.

3.2.6 No data of the project in any part/whole or its outcomes will be disclosed or published by the Investigators or any other authority of Faculty of **ICMR-NITM**. The data generated on this project will be kept confidential.

J.N. MEDICAL COLLEGE BELAGAVI

Prof. Dr. V.A. KOTHIWALE
Registrar
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नेहरू नगर, बेलगावी-५९००१० Nehru Nagar, Belagavi-590010

3.3 Responsibilities of KLEU

3.3.1 **KLEU's** J.N Medical College and Shri BMK Ayurveda Mahavidyalaya, Belagavi will conduct aforesaid research project as approved by CCRAS as per the protocol and as per the guidelines of CCRAS Research Policy.

3.3.2 The ethical clearance (from Institutional Ethics Committee) of this project will be obtained by the participating centres as appropriate for conducting the research work.

3.3.3 **KLEU's** Shri BMK Ayurveda Mahavidyalaya, Belagavi will be responsible for management of Ayurvedic intervention and overall coordination of the project.

3.3.4 **KLEU's** J.N Medical College, Belagavi will be responsible for recruitment of patients, standard treatment and clinical assessment.

3.3.4 The Investigators will be responsible for timely completion of the project with submission of detailed technical report, fund utilization certificate along with the statement of expenditure to ICMR-NITM.

3.3.5 **KLEU** will support the Monitoring Committee for monitoring of the project from time to time.

3.3.6 No data of the project in any part/whole or its outcomes will be disclosed or published by the Investigators or any other authority of Faculty of **KLEU.** The data generated on this project will be kept confidential.

3.4 Joint Responsibility

Since it is a collaborative study, the publication of the research outcomes of this study will be shared jointly by all the Parties/Stakeholders to be coordinated by the CCRAS. Research outcome of this project will be published after completion of the project.

4. Period of MoU

This MoU shall be valid for a period of Three years from the date of signing the agreement or till the completion of the project whichever is earlier, and its extension, continuation or otherwise shall be jointly decided by **CCRAS,** ICMR-**NITM** and **KLEU** two months prior to end of the above period.

5. Modification

No Modification to this MOU shall be binding unless made in writing and signed by all the parties

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

डॉ. एस. एल. होळी वैज्ञानिक-जी
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Nehru Nagar, Belagavi-590010

6. Arbitration

In the event of any dispute or differences between the parties hitherto, such differences shall be resolved amicably by mutual consultation. Where it could not be resolved so, then it shall be referred to arbitration of three arbitrators, one to be appointed by each of the parties. The two arbitrators shall appoint the Third Arbitrator (Umpire) mutually who shall preside over the proceedings. The decision of the said arbitrators shall be final and binding on all parties. The venue of arbitration shall be subject to the jurisdiction of Courts in Delhi.

IN WITNESS WHEREOF, all the Parties have set and subscribed their respective hands to this Memorandum of Understanding on the date and place first mentioned above, in the presence of following witnesses.

On behalf of CCRAS	**On behalf of ICMR-NITM**	**On behalf of KLEU**
Head of the Institute Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru	(Head of the Institution/representative)	(Head of the Institution/representative)
Signature Name Dr. Sulochana Bhat Date 09-08-2017 प्रभारी अनुसंधान अधिकारी (वे 3) क्षे.आ.प.वि.अ.सं, बेंगलुरु-11. Research Officer (S-3) In-Charge R.A.R I M D., Bengaluru-11.	Signature Name Dr. S. L. Hati Date 9/8/2017 डॉ. एस. एल. होटी वैज्ञानिक-जी Dr. S. L. Hati Scientist-G आयुर्वेदिक चिकित्साविज्ञान संस्थान ICMR - National Institute of Traditional Medicine नेहरू नगर, बेलगावी-590010 Nehru Nagar, Belagavi-590010	Signature Name Dr. V. D. Patil Date 9/8/2017
Witness 1. Signature Name Dr. Shubhashree. M.N. Address RARIMD, B'lore.	**Witness(Investigators)** 1. Signature Name Dr. Subramanya Address ICMR-NITM Belgavi.	**Witness(Investigators)** 1. Signature Name Dr BS Prasad Address KLEU BMK By Colle Belgaum
2. Signature Name Dr. V. Rama Rao Address RARIMD, Bengaluru	2. Signature Name SHRIPAD BHAT Address NITM Belagavi	2. Signature Name Dr. Sukumar. N Address KLEU BMK-Ay Belgavi

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

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Purchased by	:	CENTRAL COUNCIL FOR RESEARCH AYURVEDIC SEIENCES
Description of Document	:	Article 33 Memorandum of Association of a company
Description	:	MEMORANDUM OF UNDERSTANDING
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CENTRAL COUNCIL FOR RESEARCH AYURVEDIC SEIENCES
Second Party	:	KLE UNIVERSITY BELAGAVI
Stamp Duty Paid By	:	CENTRAL COUNCIL FOR RESEARCH AYURVEDIC SEIENCES
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

The Pavagada Coubarda Multipurpose Co-operative Limited (R)

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MEMORANDUM OF UNDERSTANDING
BETWEEN
CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES (CCRAS)
AND
KLEU SHRI BMK AYURVEDA MAHAVIDYALAYA AND HOSPITAL, BELAGAVI

This memorandum of understanding (MoU) entered into and executed on 20th Jan. 2018 Between **Central Council for Research in Ayurvedic Sciences** (hereinafter referred to as **"CCRAS"**), a society registered under the Societies Registration Act 1860, having its office at 61-65, Opp. ' D' Block, Institutional Area, Janakpuri, New Delhi of the First part.

ATTESTED

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

AND

KLEU Shri BMK Ayurveda Mahavidyalaya and Hospital, Belagavi (hereinafter referred to as **"BMKAM&H"**), having its office at Shahapur, Belagavi, Karnataka- 590 003 of the Second part

1. OBJECTIVE OF THE MOU

To carry out the Multi-centre research project entitled "***A Randomized Placebo Controlled Prospective Phase II Clinical Study of an Ayurvedic coded drug 'AYUSH D' on Glycemic control in Prediabetic Subjects***" as per the terms and conditions and guidelines of CCRAS Research Policy.

2. PROPOSED MODES OF COLLABORATION

CCRAS and **BMKAM&H** propose to collaborate through:

2.1 Undertaking the research project entitled "***A Randomized Placebo Controlled Prospective Phase II Clinical Study of an Ayurvedic coded drug 'AYUSH D' on Glycemic control in Prediabetic Subjects***" with duration of **Two and half years.**

2.2 Research work will be carried out at **BMKAM&H** premises wherein **Dr. B.R.Tubaki Professor, Department of Kayachikitsa** will be the Principal investigator.

3. Both **CCRAS** and **BMKAM&H** are interested in collaborating with each other to facilitate the execution of this project with sharing of following responsibilities:

3.1 Responsibilities of CCRAS

3.1.1 CCRAS agrees for multicentre research project entitled "*A Randomized Placebo Controlled Prospective Phase II Clinical Study of an Ayurvedic coded drug 'AYUSH D' on Glycemic control in Prediabetic Subjects*" with BMKAM&H.

3.1.2 Standardized Coded Ayurvedic drug and the matching placebo will be provided by CCRAS for the clinical trial.

3.1.3 Entire funding for the proposed project will be extended by CCRAS while the execution of the project will be done at BMKAM&H as per the guidelines of CCRAS Research Policy.

3.1.4 The fund will be released in the name of the Principal, BMKAM&H.

3.1.5 A Monitoring Committee (consisting of three/four members) nominated by DG-CCRAS /his representative (the funding agency) will monitor the project from time to time.

3.2 Responsibilities of BMKAM&H

3.2.1 BMKAM&H will conduct aforesaid research project as approved by CCRAS as per the protocol and as per the guidelines of CCRAS Research Policy.

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

3.2.2 The ethical clearance (from Institutional Ethics Committee) of this project will be obtained by BMKAM&H for conducting the research work.

3.2.3 The Investigators will be responsible for timely completion of the project with submission of detailed technical report, fund utilization certificate along with the statement of expenditure.

3.2.4 BMKAM&H will support the Monitoring Committee for monitoring of the project from time to time.

3.2.5 No data of the project in any part/whole or its outcomes will be disclosed or published by the Investigators or any other authority of Faculty of BMKAM&H. The data generated on this project will be kept confidential.

3.3 Joint Responsibility

Since it is a Multi centre study, the publication of the research outcomes of this study will be shared jointly by all the Parties/Stakeholders to be coordinated by the CCRAS. Research outcome of this project will be published after completion of the project. All IPR issues will lie with the CCRAS.

4. Period of MoU

This MoU shall be valid for a period of Three years from the date of signing the agreement or till the completion of the project whichever is earlier, and its extension, continuation or otherwise shall be jointly decided by CCRAS and BMKAM&H two months prior to end of the above period.

5. Arbitration

In the event of any dispute or differences between the parties hitherto, such differences shall be resolved amicably by mutual consultation. Where it could not be resolved so, then it shall be referred to arbitration of three arbitrators, one to be appointed by each of the parties. The two arbitrators shall appoint the Third Arbitrator (Umpire) mutually who shall preside over the proceedings. The decision of the said arbitrators shall be final and binding on both the parties. The venue of arbitration shall be subject to the jurisdiction of Courts in Delhi.

IN WITNESS WHEREOF, both the Parties have set and subscribed their respective hands to this Memorandum of Understanding on the date and place first mentioned above, in the presence of following witnesses.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

On behalf of CCRAS

Head of the Institute
Regional Ayurveda Research Institute for Metabolic disorders, Bengaluru

Signature
Name Sulochana Bhat
Date 20-01-2018

On behalf of BMKAM&H

(Principal or representative of the Institution)

Signature
Name
Date

Prof. Dr. V. D. PATIL
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

Witness

1.Signature 20/1/18
Name Dr. Amit Kumar Dixit
Address RARIMD, CCRAS
Bengaluru-560011

2. Signature 20.1.18
Name DR. KISHORE KUMAR R
Address RARIMD - CCRAS
BENGALURU

Witness(Investigators)

1.Signature
Name
Address

PRINCIPAL
Shri B. M. Kankanawadi
Ayurved Mahavidyalaya
A Constituent Unit of KAHER
Shahapur, BELAGAVI-03.

2. Signature
Name DR A.A. TUBAKI
Address Professor and Head of Kayachikitsa
KLE's BMK Ayurveda mahavidyalaya, Belagavi

क्षेत्रीय आयुर्वेदीय चयापचय विकार अनुसंधान संस्थान
(सी.सी.आर.ए.एस., आयुष मंत्रालय, भारत सरकार)
स.कें.औ. उपभवन, अशोक स्तंभ, जयनगर, बेंगलुरु-560 011.
Regional Ayurveda Research Institute for Metabolic Disorders
(C.C.R.A.S., Ministry of AYUSH, Govt. of India)
G.C.P. Annexe, Ashoka Pillar, Jayanagar, Bengaluru-560 011

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

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Purchased by	:	DR BHAGYASHRI PATIL
Description of Document	:	Article 12 Bond
Description	:	UNDERTAKING
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First Party	:	DR BHAGYASHRI PATIL
Second Party	:	MD AND CEO KLES DR PRABHAKAR KORE HOSPITAL AND MRC
Stamp Duty Paid By	:	DR BHAGYASHRI PATIL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatory
For Awami Urban Co-op. Credit Society Ltd., Belagavi

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TO,

THE M D & CE,

KLE'S DR.PRABHAKAR KORE HOSPITAL & MRC,

NEHRU NAGAR, BELAGAVI-590010

ATTESTED

SUBJECT: UNDERTAKING REGARDING HANDLING OF FINANCES FROM THE CLINICAL TRIALS AND RESEARCH PROJECT BY DR. BHAGYASHRI PATIL.

Registrar
KLE Academy of Higher Education and Research, BELAGAVI

Sir,

I DR. BHAGYASHRI PATIL the undersign is Principal investigator for the clinical trial and the Phase 3 Study for Prospective, Multi-Centric, Double Blind, Parallel Group, Active Controlled Randomized Study to Evaluate the Efficacy and Safety of Bilastine in Adult and Adolescent Patients with Seasonal Allergic Rhinitis. I have Co-Investigator is Dr. Shama Bellad Research Coordinator is Miss Snehal Wandre.

I hereby give an undertaking that I will conduct the investigations/clinical trials as per the agreed terms and deposit 20% of the total funds (as and when received from time to time) to the second party (Medical Director & CE KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi) to the institution as mentioned in the Judicial agreement made. The payment from sponsors

I will maintain records of all the receipts from the third party as well as payments to second party throughout the trial period and submit a final report about the finances including institutional charges, when I conclude the trial. The payments if any, to the associated staff will also be clearly brought out in the periodical reports.

Date: 2 Jan 2018

Signature of PI

Dr. BHAGYASHRI PATIL
CONSULTANT PULMONOLOGIST
KMC Reg. No. 62951

Place: Belagavi

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

SMT. K. ANITHA
S.V.L.NO. 56/96,R.L.NO.....
H.NO. 26/C
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TELANGANA

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("The Agreement") is made and executed on 28th November 2017 by and between

HETERO LABS LIMITED (hereinafter referred to as "SPONSOR"), with its CIN # *U24110TG1989PLC009723* 7-2-A2, Hetero Corporate, Industrial Estates, Sanathnagar, Hyderabad – 500 018, Telangana State, India, a company registered under the companies Act 1956, represented by its Director and hereinafter called "Sponsor" (which expression unless repugnant to the subject or context therein shall mean and include its assignees, affiliates, employees, subsidiaries, nominees, agents and successors-in-interest) of the one part;

And

CLINSE LABS PRIVATE LIMITED a Company incorporated under the Companies Act, 1956 with its CIN # *U24239AP2005PTC047265* and having its Registered at 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad – 500018 (hereinafter referred to as "**CRO**", which expression shall unless repugnant to the context or meaning thereof shall mean and include its successors and permitted assigns) of the Second Part

And

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Dr. Patil Bhagyashri Bhimgonda, KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India Hereinafter referred to as the "Principal Investigator" (which expression unless repugnant to the subject or context therein shall mean and include his heirs, executors and successors-in-interest) of the Third part,

And

KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India Hereinafter referred to as the "Institution" (which expression unless repugnant to the subject or context therein shall mean and include his heirs, executors and successors-in-interest) of the Fourth part,

And

KV Clinical Research Services, MIG II/253 Sector -1,Pt.Deendayal Upadhyay Nagar, Raipur-492001, Chhattisgarh hereinafter referred to as the "Site Management Organization" Hereinafter referred to as the "SMO" (which expression unless repugnant to the subject or context therein shall mean and include his heirs, executors and successors-in-interest) of the Fifth part

"Sponsor", "CRO" ''Investigator", "Institution" and "SMO" are hereinafter collectively referred to as 'Parties" and individually as a "Party".

WHEREAS

The Sponsor has appointed CRO for conducting a clinical trial entitled, Study title: -

" A Prospective, Multi-Centric, Double Blind, Parallel Group, Active Controlled Randomized Study to Evaluate the Efficacy and Safety of Bilastine in Adult and Adolescent Patients with Seasonal Allergic Rhinitis (Exhibit A)

A. A. Vide letter dated 23rd Aug 2017, the Principal Investigator agreed to conduct the aforesaid Clinical Trial at **KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India.** Adult and Adolescent Patients with Seasonal Allergic Rhinitis to confirm the efficacy and tolerability and Safety of the aforesaid drug.

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B. SPONSOR is the owner of Protocol and is desirous and willing to conduct this Clinical Trial through the CRO herein by engaging the PRINCIPAL INVESTIGATOR.

C. AND WHEREAS the institution is equipped and qualified to undertake the study and Institution and Principal Investigator have agreed to perform the study on the terms and conditions hereinafter set forth

D. CRO has confirmed its ability to perform the Services designated by Sponsor in accordance with terms and conditions of the Clinical Service Agreement and the applicable provisions of law, guidelines, the standards and practices that are generally accepted in the industry in performing similar services including but not limited to the terms and conditions of this Agreement.

E. CRO further agreed to act professionally and responsibly as the necessary interface between the Principal Investigator, Institution, Site and SPONSOR;

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

1.0 The Clinical Trial Period shall be approximately 06 months from the date of this agreement, which may be extended by mutual consent in writing.

2.0 The Principal Investigator will conduct the Clinical Trial strictly as per Protocol ID No. HCR/III/BISAR/03/2017 (Annexure I) ("Clinical Trial Protocol") as approved by the Institutional Ethics Committee in accordance with applicable regulatory requirements.

2.1 The Principal Investigator confirms that he has studied and understood the Clinical Trial Protocol and has agreed to conduct the Clinical Trial according to the guidelines prescribed by the Drugs Controller General India.

2.2 The Principal Investigator hereunder shall perform the Study at the Clinic/ hospital/ Institution mentioned in the investigator undertaking. The following person shall be acting as collaborators if applicable, in the conduct of the study and agree to be bound by the terms of this Agreement (the "collaborators")

2.3 The Principal Investigator further represent, warrant and covenant that the Principal Investigator is and at all times, during the term of this Agreement, shall be: (a) in good

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

professional standing, (b) in possession of all requisite professional licenses, (c) fully qualified to conduct the Study and to act as the Principal Investigator under the Agreement, (d) fully experienced and knowledgeable with respect to all matters pertaining to the study and (e) responsible for the supervision of all persons who may assist the Principal Investigator or otherwise be engaged in the study. The Principal Investigator shall be responsible for the performance of the study as per the highest standards of medical and clinical research practices. Prior to commencing the Study, Principal investigator shall require and each Collaborator engaged in the Study to complete and return to SPONSOR the Disclosure of Financial Interests and Arrangements, if any, in the study.

2.4 The Principal Investigator agrees to use his / her best efforts and professional expertise to perform the Study in accordance with the Protocol and the terms and conditions of this Agreement. In the event SPONSOR do not approve, SPONSOR may terminate this Agreement in accordance with the Termination section below and Institution shall take all necessary steps to effectuate such termination.

2.5 The Principal Investigator agree to ensure to his best efforts that no subject in this study may participate concurrently in any ancillary study (technique, procedure, questionnaire or observation other than those set forth in the Protocol) without prior approval in writing from SPONSOR. In the event that SPONSOR approves such participation, the Principal Investigator agree that the ancillary study will be conducted in accordance with all applicable Laws, Rules and Regulations, including but not limited to Schedule Y to Drugs & Cosmetics Rule 1945 under Drugs & Cosmetics Act 1940, Guidelines of Indian Council for Medical Research, India Good Clinical Practice of the Central Drugs Standards Control Organization, ICH Guidance for Good Clinical Practice, Declaration of Helsinki. Principal Investigator agree to provide SPONSOR periodically and in a timely manner during the term of this Agreement with all Clinical Trial results and other data called as per the Protocol on properly completed (written or electronic) Case Record Forms.

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2.6 Principal Investigator agree to report to SPONSOR all SAEs and important medical events, as identified in the protocol, affecting any trial subject in the Clinical trial as per applicable regulatory guidelines (including but not limited to schedule Y guidelines). Principal Investigator further agrees to follow up such report with detailed written reports in compliance with all applicable legal and regulatory requirements.

2.7 The Principal Investigator undertakes to indemnify and hold harmless the Sponsor, its directors, employees and agents from any claims, demands, costs or judgments against them resulting from their failure and/or the failure of their employees and/or the agents of KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India to adhere to the terms of this agreement or procedures/terms of the protocol for the trial and/or failure to comply with any/all applicable laws, regulations, guidelines and/or from the wrongful/ unauthorized use of the Clinical Trial Drug and/or from the data/information/ result/reports submitted to Sponsor and/or from acts of negligence, malice, fraud by Principal Investigator and/or the employees and/or the agents of KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India

The Sponsor appoints Dr. Neetu Naidu Rayala Clinical Development & Medical Affairs as Monitor for the Clinical Trial and reserves its right to nominate any other person as Monitor.

The Sponsor will supply the aforesaid Drug to the Principal Investigator free of cost, case record forms, consent forms, patient information sheets and other stationery as may be required. The Sponsor will bear the Consultation Charges, Research Assistant Fee, Laboratory Investigation charges, other miscellaneous and sundry expenses as detailed in Annexure III. All amounts will be paid by means of crossed cheque with available payee details.

The Sponsor has to provide appropriate Instruments/Equipments to conduct the study at site. In case of injury or death during a clinical trial, patient shall be given free medical management as long as required by the sponsor.

In case the injury occurring to the clinical trial subject is related to the clinical trial, the subject or the subject's nominee(s) shall also be entitled for financial compensation as

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per order of Licensing Authority defined under clause (b) of rule 21 and the financial compensation will be over and above any expenses incurred on the medical management of such subject.

The expenses on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

The Sponsor undertakes to indemnify and hold harmless Principal Investigator and other employees of, KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India who are directly involved in the Clinical Trial under their supervision, from any claims, demands, costs or judgments arising out of adverse reactions to the patients on Clinical Trial involving the Clinical trial Drug provided, however, the Sponsor shall not be responsible for any liability, loss or damages resulting from a failure by Principal Investigator and/or the employees and/or the agents KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India to comply with the terms of this agreement or any/all applicable laws, regulations, guidelines and/or acts of malice, negligence, or fraud.

3.0 Dispute Resolution:

This Agreement shall be governed by and shall be construed in accordance with Indian Laws. The Parties agree that they shall in good faith work towards implementation of this Agreement and any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which such dispute shall be referred to Arbitration in terms of Arbitration & Conciliation Act, 1996. All disputes, controversies or claims arising out of or relating to this Agreement including interpretation thereof, or breach, termination or invalidity thereof shall be referred to arbitration to a sole arbitrator to be appointed mutually by the Sponsor and the Institution. The Venue of Arbitration at Hyderabad and the Arbitration proceedings shall be conducted in English language. The decision of such arbitrator shall be final, binding and conclusive on the Parties.

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4.3 Term. The validity of the agreement is for a period of four years from the date of the agreement or the completion of the Clinical Trial, whichever is earlier.

5.0 Termination: This agreement may be terminated-

5.1 By either party if the other party commits breach and fails to remedy such breach within 30 days from the date of receipt of written notice detailing the same. The other party on receipt of the notice shall immediately take all steps to cease conduct of the trial as soon as possible to protect the welfare of subjects participating in the trial. Further, either party may terminate this Agreement with immediate effect by written notice to the respective party if the Investigator is no longer available and Institution and the Sponsor fail to appoint an Investigator mutually.

5.2 By Sponsor with 30 days prior written notice:
Sponsor, in its sole discretion, shall have the right to terminate agreement and stop the conduct of the trial at any time by giving notice to the principal investigator accordingly

5.3 Termination by the Institution / Investigator:
Institution / Investigator shall have the right to terminate the conduct of the trial if necessary to protect the welfare of the subjects by giving notice to sponsor.

Respective obligation in the event of early termination: If the trial is terminated prior to its completion, the Sponsor shall pay to the remuneration detailed in the Agreement by the milestones that have been duly achieved to the date of termination. In the case of early termination of the trial for any reason, the Institution / Principal Investigator shall provide all such assistance as Sponsor shall reasonably require to ensure an efficient handover of conduct of trial to a third party and with due regard for the welfare of the subjects.

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Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Return of Material: Principal Investigator shall return to SPONSOR any unused Study Drug and all SPONSOR Confidential Information, as defined in the Confidentiality Section of this Agreement, on the conclusion of the Study or termination of this Agreement as the case may be.

6.0 Ownership of Data, Confidentiality and Publication:

6.1 Ownership. All case report forms and other data (including without limitation, written, printed, graphic, video and audio material and information contained in any computer data base or computer readable form) generated by the Principal Investigator in the course of conducting the Study (the "Data") shall be property of SPONSOR, which may utilize the Data in any way it deems appropriate, subject to and in accordance with all applicable (a) Indian laws and regulations and (b) privacy and security laws of India and other countries. Any copyright work created in connection with performance of Study and contained in the Data (except any publication by the Principal Investigator as provided for hereinafter) shall be property of SPONSOR as the author and the owner of copyright in such work

6.2 All information, including, but not limited to, the Study Drug or SPONSOR operations, such as SPONSOR's patent applications, formulas, manufacturing processes, basic scientific data, prior clinical data and formulation information supplied by SPONSOR to and/or Principal Investigator and not previously published (the "SPONSOR Confidential Information") are considered confidential and shall remain the sole property of SPONSOR. Both during and after the term of this Agreement, and Principal Investigator will use diligent efforts to maintain in confidence and use only for the purposes contemplated in this Agreement (i) the information which is identified in the preceding sentence as confidential or which a reasonable person would conclude as confidential and proprietary property of SPONSOR and which is disclose by or on behalf of Principal Investigator and (ii) Data which is generated as a result of this Study. The preceding obligations shall not apply to data or information (i) which has been published through no fault of Investigator, or (ii) which SPONSOR agree, in writing, may be used or disclosed, or (iii) which is published in accordance with paragraph C of this Section (iv). The provisions in this paragraph shall survive the termination or expiration of this Agreement for a period of ten years.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

6.3 Publication: The Principal Investigator acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor which is disclosed to the Principal Investigator is and shall always remain the sole and exclusive property of Sponsor. The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the Principal Investigator may publish data generated at their (own) site, only after getting written approval from Sponsor and only after the first publication of such data by the Sponsor or as mutually agreed by the Parties.

6.4 Patents: All rights to any discovery or invention conceived and reduced to practice as a result of the work conducted under this Agreement shall belong to SPONSOR. The Principal Investigator agree to assign to SPONSOR, the sole and exclusive ownership thereto, upon the payment of costs by SPONSOR, if any, incurred by principal investigator in assisting SPONSOR in their filling, prosecution, or maintenance of any patent application or patent issued thereon. Such patent applications, if any, shall be filed and prosecuted by SPONSOR. Principal Investigator shall promptly disclose to SPONSOR any invention or discovery arising under this Agreement. Principal Investigator shall execute and shall have its employees execute all documents necessary to transfer all rights, titles and interests in and to any such invention or discovery to SPONSOR.

7.0 Data Use Agreement:

7.1 Encoding study data: Principal Investigator shall ensure that the patient identifiable information that is disclosed during the study and provided to the SPONSOR under this study fulfilled all privacy obligations under applicable legislations and regulations.

7.2 SPONSOR use of data set: SPONSOR shall not use or disclose information that would violate the requirements of any privacy legislation. SPONSOR will limit access to the data to personnel responsible for research and development function within their respective organization or within affiliated companies of SPONSOR. SPONSOR may also provide access to contract research organizations and other consultants or agents working with the research and development functions of these entities on the research activities detailed above. SPONSOR will ensure that all such

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parties assume the data protection responsibilities of SPONSOR as set forth in paragraph (c) of this section.

7.3 Protection of the data. SPONSOR shall, with respect to the information continued in the data (i) not use or further disclose the information other than as permitted or required by this agreement or as otherwise required by law; (ii) use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement; (iii) report to Principal Investigator any use or disclosure of information not provided for by this agreement of which it becomes aware; (iv) ensure that any agent or assignee, including a subcontractor, to whom it provides the information agrees to the same restrictions and conditions that apply to SPONSOR with respect to the data and (v) not identify the information or contracts of the individuals to whom it pertains.

8.0 Insurance

8.1 SPONSOR shall secure and maintain in full force and effect, through the performance of the study (and following termination of the study to cover any claims arising from the study) Insurance coverage for general liability in amounts appropriate to the conduct of business activities and the services contemplated by the study.

8.2 Principal investigator shall secure and maintain in full force and effect, through the performance of the study (and following termination of the study to cover any claims arising from the study) Insurance coverage for medical, professional and medical malpractice liability, in amounts appropriate to the conduct of business activities and the services contemplated by the study.

8.3 Upon request, each party shall provide to the other party a copy of the insurance certificate setting forth the foregoing coverage.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar

3. In case of any discrepancy please inform the Competent Authority. Higher Education and Research, BELAGAVI

9. Debarment / Financial Disclosure: Principal investigator shall not employ, contract with or retain any person directly or indirectly to perform service under this Agreement if such a person incurs any disqualification of any nature under any statute in force either in India. Upon written request from SPONSOR, principal investigator shall, within ten days, provide written confirmation that it has complied with the foregoing obligation. Principal investigator shall also provide to SPONSOR all information necessary to comply with any disclosure requirements mandated Drugs & Cosmetics Act 1940, including any information required to be disclosed in connection with any financial relationship between SPONSOR and Principal Investigator. This disclosure requirement shall require disclosure of information involving immediate family members of those involved in the study.

10. Independent Contractor: Principal Investigator act in the capacity of independent contractor hereunder and not as agents or employees of SPONSOR. The Principal Investigator will make no claim against SPONSOR for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers compensation, disability or unemployment benefits or employee benefits of any kind, including right/status as an employee of SPONSOR.

11. Publicity: None of the parties shall use the name of any other party for promotional purposes without the prior written consent of the party whose name is proposed to be used nor shall either party disclose the existence or substance of this Agreement except as required by law.

12. Agreement Modifications: This Agreement or any of its Exhibits shall not be altered, amended or modified except by written document signed by all parties Hereto.

13. Assignment: SPONSOR shall have the right to assign this Agreement to an affiliate of SPONSOR upon prior written notice to Principal investigator. In all other instances, neither party shall assign its rights or duties under this Agreement to another without prior written consent of the other party. Subject to the foregoing, this Agreement shall bind and inure to the respective parties and their successors and assigns.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

14. Conflict with protocol: If any of the provisions of this Agreement conflict with any provision of the protocol, this Agreement shall take precedence.

In witness whereof, the parties have caused this agreement to be executed by their authorized representative on the date, month and year first above mentioned

Hetero Labs Limited

Dr. Shubhadeep Sinha
Authorized Signatory

HETERO LABS LIMITED * HYDERABAD *

Hetero Labs Limited

28/12/2017

M. Jayapal Reddy
DGM-Legal

Clinse Labs Private Limited

B. Mohan Reddy
Senior Manager – Clinical Research

KLES Dr Prabhakar Kore Hospital&
Medical Research Centre

2/1/2018

Authorized Signatory

Principal Investigator

B3patil 2 Jan 2018

Dr. Patil Bhagyashri Bhimgonda

Dr BH
CONS
KMC

DDIST

KV Clinical Research Services

Dr. Vikas R Chandrakar
Managing Director

ATTESTED

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Annexure I

DCGI NOC

(Attached Separately)

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Annexure II

CLINICAL TRIAL PROTOCOL

(Attached Separately)

ATTESTED

Prof. P. V. A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Annexure- III

PAYMENT TERMS AND SCHEDULE

Estimated cost per one completed patient:

S.No	Details	Per Visit	Visit	No. of Visits	Total
1	Investigator Consultation Charges	2000	1	4	8000
2	12 Lead ECG	500	1	4	2000
3	Patient Conveyance	500	1	4	2000
4	Institutional charges [20% of items 1]				1600
	CRC Fee	V1(800),V2(700),V3(700),V4(800)			
	Total Cost of the project for 1 completed patient				13600

1. **Payment terms:**

a. Payments will be made every month as per the invoice received against e-CRF Completion and all queries should be resolved for completed visits.

b. Payment of Rs. 50,000/- will be paid as an advance after signing the agreement before or after the site Initiation visit. This amount will be adjusted in the subsequent invoices received.

c. The final payment to the site will be paid based on the number of patients enrolled, completed, Withdrawn/dropout and screen failures before the site closure visit.

d. If the site is terminated or doesn't progress in terms of recruitment for at least 3 months after Initiation / paying the advance, then the amount paid should be returned by the PI/Institution to the Sponsor after making necessary deductions and adjustments.

e. The archival of study documents after site closeout and the complete responsibility hold with the Sponsor/CRO for 15 years.

f. GST as per applicable government rules

g. TDS will be deducted at final payment (after deduction of GST) as per income tax applicable rules

h. Screen failure cost as per completed screening visit

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

2. **Payee Details :**

The CRO will make the payment after tax deduction at source. The account payee crossed cheques will be issued in

Payee Name	KV Clinical Research Services
Payee Address	KV Clinical Research Services, MIG II/253 Sector -1,Pt.Deendayal Upadhyay Nagar,Raipur-492001, Chhattisgarh
Tax ID Number (PAN Number)	AAPFK7058P
GSTIN	**22AAPFK7058P1ZM**

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, Deemed-to-be-University

CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); and Dr.Niranjana Mahantshetti, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Order shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20140444 entitled "A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of Denosumab in Pediatric Subjects With Glucocorticoid-induced Osteoporosis", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees',(including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within five (5) business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within five (5) business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: Prolia® ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company under this Order.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will reimburse the Site for the cost of the Required Material(s) as detailed in a proper invoice. Such purchase or reimbursement costs shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company under this Order. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

3.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop . Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop .

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop .

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Dr. Niranjana S Mahantashetti "**Payee**"
TAX ID	ABCPN5383J

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement and this Order, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article; "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 23rd Jan 18

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

(signature)

By: DR M.V. Kuli

(print or type name)

Title: MD & CE

Date: 16 Feb 2018

DR.NIRANJANA MAHANTSHETTI

(signature)

By: DR NIRANJANA MAHANTSHETTI

(print or type name)

Title: PRINCIPAL INVESTIGATOR

Date: 29 JAN 2018

ATTESTED

ATTESTED

Prof Dr V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Protocol Number	20140444
Site Number	30005
Investigator	Dr. Niranjana Mahantshetty
Contract Number	
Number of Subjects	4
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 1,92,282	4	Subject(s)	INR 7,69,128
SUBJECT RADIOLOGY FEES				INR 29,200
SCREEN FAILURES	INR 21,831	3	per Site	INR 65,493
ADDITIONAL SUBJECT FEES				INR 1,29,000
ADMINISTRATIVE FEES				INR 41,400
CONTRACT TOTAL				INR 10,34,221

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs and laboratory costs*

SUBJECT FEES (20% Hospital overhead)

VISIT TABLE: STUDY	Schedule A
Screening Day -35 to -1	INR 21,831
Day 1 Visit	INR 18,368
Day 10 Visit	INR 9,030
Day 30 Visit	INR 9,030
Month 3 Visit	INR 11,830
Month 6 Visit	INR 19,905
Month 12 Visit	INR 23,168
Month 18 Visit	INR 19,905
Month 24 Visit	INR 21,605
Month 30 Visit	INR 14,705
Month 36/ET Visit	INR 22,905
SUBJECT VISIT TABLE SUBTOTAL(S)	Schedule A
Per Subject Fee - Treatment	INR 1,54,672
Per Subject Fee- LTFU	INR 37,610
MAXIMUM PER SUBJECT FEE	INR 1,92,282

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel (1,000.00 INR) and meal (400.00 INR) reimbursement for each protocol required in-clinic visits

RADIOLOGY FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
X-Ray Knee	INR 500	7	per Subject	INR 14,000
X-Ray Dental Single view	INR 800	2	per Subject	INR 6,400
DXA Hip (Sreening or Day 1)	INR 1,700	1	per Subject	INR 6,800
X-Ray Spine (Screening or Day 1)	INR 500	1	per Subject	INR 2,000
SUBTOTAL, RADIOLOGY FEES				INR 29,200

** X Ray Knee to be performed only in children with open growth plates who do not have bilateral hardware*
**DXA hip could be performed at Screening or Day 1*
**X Ray Spine could be performed at Screening or Day 1*
**X Ray Dental Single View to be performed based on visual inspection*

VISIT TABLE: SCREEN FAILURE	Schedule A
Screen Failure	INR 21,831
MAXIMUM SCREEN FAIL	INR 21,831

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ADDITIONAL SUBJECT FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
Infrastructure Fee	INR 75,000	1	per Site	INR 75,000
ISD Line Rental	INR 1,500	36	per Site	INR 54,000
SUBTOTAL, ADDITIONAL SUBJECT FEES				**INR 1,29,000**

Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be optained by site from study team before placing order for the infrastucture.
ISD line charge will be provided on monthly basis after site initiation untill final monitoring visit.

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
Document Storage, Archiving Total Cost	INR 41,400	1	per Site	INR 41,400
SUBTOTAL, ADMINISTRATIVE FEES				**INR 41,400**

Archival fee will be paid at the time of site close-out

PAYMENT DISTRIBUTION

Initial Payment	**50,000.00** *Amgen will pay Institution this initial payment upon execution of the Agreement. In orc to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Dr. Niranjana S Mahantashetti' (Tax id ABCPN5383J)
The EC for this study will be 'Ethics Committee of KLE University' and the payment of the EC fees will be made in the favor of 'Registrar, KLE University, Belagavi'.

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors (including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale
2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

This Clinical Trial agreement made between:

Dr. Richard Saldanha, Chief Cardiothoracic Surgeon, KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India

(PI/Investigator),

And

KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India

And

Phoenix Cardiac Devices Pvt. Ltd, having a place of business at # 1-7-23/26, JSN Colony, Street No: 8, Habsiguda, Hyderabad - 500 007 T.S., India (the Sponsor).

PROTOCOL NUMBER:	**BACE – CT003**
PROTOCOL TITLE:	**Evaluation of safety and efficacy of the BACE™ [Basal Annuloplasty of the Cardia Externally] device in the treatment of Functional Mitral Valve Regurgitation (FMR)**
PROTOCOL DATE:	**BACE CT003; Version No. 1.2, dated: Nov 18, 2017**
SPONSOR:	**Phoenix Cardiac Devices Pvt. Ltd**
PRINCIPAL INVESTIGATOR:	Dr. Richard saldanha

WHEREAS, the Investigator and Institution, if any, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (Study), in accordance with the above-referenced protocol and any subsequent amendments thereto (Protocol) and Phoenix Cardiac Devices Pvt Ltd requests the Site to undertake such Study;

NOW THEREFORE, the following is agreed:

1 Sponsor hereby appoints the Site to conduct the Study, and the Site agrees to ensure that the Site and the Site's employees, agents, and staff will conduct the Study in accordance with the Protocol, the terms of this agreement, including the Terms and Conditions attached as Attachment A, the Payment Schedule and Budget attached as Attachment B, and any other the attachments hereto, which all are incorporated by reference herein (Agreement), good clinical practices, and all applicable laws and regulations. The Site hereby confirms that it has adequate time and resources to perform the Study according to the quality standards required.

2 Payments shall be made in accordance with the provisions set forth in Attachment B, with the last payment being made upon successful completion of the Study and submission of all Case Report Forms Modules in-house and submission of final Study report in terms of the Protocol and, if sponsor requests, all other Confidential Information as defined in Attachment A, Article 2 (Confidential and Proprietary Information). The Site will act as an independent contractor, and Sponsor shall not be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site. The Site acknowledges and agrees that Investigator's judgment with respect to Investigator's advice to and care of each subject is not affected by the compensation Site receives hereunder. The parties agree that the payee (Payee)designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following Payee:

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PAYEE NAME:	**CMS Clinical research Pvt. Ltd.**
PAYEE ADDRESS:	**Inox Tower-B, Plot No. 17, Sector 16A, Film City, Noida, India 201301**
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	**AAFCC8457M**

It should be noted that all the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country and Sponsor will deduct the tax at the time of making payments if required by the tax laws.

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

The parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement. **Investigator acknowledges that if Investigator is not the Payee, Sponsor will not pay Investigator even if the Payee fails to reimburse Investigator.**

3. This Agreement will become effective on the date on which it is last signed by the parties In the event of a conflict between the Protocol and this Agreement; the terms of the Agreement will govern.

ACKNOWLEDGED AND AGREED BY

For and on Behalf of Phoenix Cardiac Devices Pvt. Ltd

Authorised Signatory: **Gopal Muppirala, CEO**

Jan 30th, 2018
Date

ACKNOWLEDGED AND AGREED BY

Name of ~~the Principal Investigator~~: Dr. Richard saldanha

Dr. Richard Saldanha
MS.,MCh.,DNB.
Chief Cardio Thoracic Surgeon
KLES Dr. Prabhakar Kore Hospital &
Medical Research Center,
Nehru Nagar, BELAGAVI - 10.
Reg. No. KMC 19161

31/1/2018
Date

ACKNOWLEDGED AND AGREED BY

For and on Behalf of KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India

Authorised Signatory:
Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

05/02/18
Date

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ATTACHMENT A TERMS AND CONDITIONS

1) **Conduct of the Study.** The parties to the attached agreement (the "Agreement") agree that the clinical trial described therein (Study) will be performed in strict accordance with the applicable protocol, and any subsequent amendments thereto applicable federal, state, and local laws, regulations and guidelines, and good clinical practices (GCPs).

The Principal Investigator (PI/Investigator) will provide copies of the CIP and all pertinent information to the study personnel, will discuss this material with them, and will ensure they are fully informed regarding the device and the conduct of the study.

The Investigator shall review all case report forms (CRFs) to ensure their accuracy and completeness, shall review and understand the information in the investigator's brochure or device labeling instructions, as applicable, shall ensure that all informed consent requirements are met, and shall ensure that all required reviews and approvals (or favorable opinions) by applicable regulatory authorities and Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs) are obtained.

The Investigator and the institution(s), conducting the trial (jointly, Site) agree to ensure that all clinical data are accurate, complete, and legible. The Site shall promptly and fully produce all data, records and information relating to the Study to Sponsor or their designee (CRO to be named) and their representatives during normal business hours, and shall assist them in promptly resolving any questions and in performing audits or reviews of original subject records, reports, or data sources.

The Site agrees to cooperate with the representatives of Sponsor who visit the Site, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for, such representatives.

The Site shall use the device being tested (the Investigational Product), provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Investigational Products in a locked, secured area at all times. Upon completion or termination of the Study, the Site shall return all unused Investigational Products, equipment, and materials and all Confidential Information (as defined below).

2) **Disclosure of Protected Health Information [Patient Privacy]:**

During the course of this study, the research team [e.g., Investigators, study Coordinators, Medical Monitors, data analysts] will be collecting protected health information. The research team will take appropriate steps to keep protected health information private when possible, and it will be protected according to state and federal Law. This patient information will only be shared with the parties named below, per the requirements of health Canada. These may include federal agencies, the Sponsor, or the IRB; these entities might view or receive this information to collect data or to meet legal, ethical, research, and safety-related obligations. The authorization for Informed Consent and will expire at the end of the study.

3) **Confidential and Proprietary Information.**

All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Investigational Product), provided to the Site by Sponsor, or their designees, (whether verbal, written or electronic), and all

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data, reports and information, relating to the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor.

The Site shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. These confidentiality obligations shall continue until fifteen (15) years after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Site; b) is disclosed to the Site by a third party not subject to any obligation of confidence; c) must be disclosed to IRBs, IECs, or applicable regulatory authorities; d) must be included in any subject's informed consent form; e) is published in accordance with Article 3 herein; or, f) is required to be disclosed by applicable law.

4) **Intellectual Property.**

The existing inventions and technologies of Sponsor, or the Site are their separate property and are not affected by this Agreement. Sponsor shall have exclusive ownership of any inventions or discoveries arising in whole or in part from Confidential Information or arising as a result of the Study. The Site will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to obtain patents in any country or to otherwise protect Sponsor's interests in such inventions or discoveries.

The Site shall have exclusive ownership of any inventions or discoveries conceived by the Site during the time that the Study is taking place that do not arise in whole or in part from the Study or any Confidential Information, but the Site shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions or discoveries. The Site agrees to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

In the event of a dispute, inventorship of any inventions, developments, or discoveries, whether patentable or not (Collectively referred to as "Intellectual Property"), resulting from the performance of the study, shall be allocated according to U.S. Patent Law (Title 35 U.S. Code) in effect at the time the intellectual property was created.

5) **Publication.**

Sponsor has no objection to publication by institute of the results of the study based on information collected or generated by institution, whether or not the results are favorable to sponsor. However, to ensure against inadvertent disclosure of confidential information or unprotected inventions, at least thirty (30) days before submitting or presenting a manuscript or other materials relating to the study to a publisher, reviewer, or other outside persons, the site shall provide to sponsor a copy of all such manuscripts and materials, and allow sponsor thirty (30) days to review and comment on them.

If any patent action is required to protect inventions, institution agrees to delay the disclosure for a period not to exceed ninety (90) days from the date institution initially submitted the proposed publication, or other type of disclosure, to sponsor for review.

The Site shall remove any Confidential Information (other than Study results) prior to submitting or presenting the materials, if Sponsor requests. No party hereto shall use any other party's name, or Sponsor's name, in connection with any advertising, publication or promotion without sponsor's prior written permission.

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If Study is part of a multi-centre study, Institution agrees that the first publication is to be a joint publication covering all centres. However, if a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of study at all participating sites, institution is free to publish its results separately.

6) **Inspection and Debarment.**

When given reasonable notice, the Site agrees to allow Sponsor, or their designee, or regulatory authority personnel direct access to the Site's records relating to the Study, including subject medical records, for monitoring, auditing, and inspection purposes. The Site shall immediately notify the Sponsor of this, and provide the Sponsor copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit the Sponsor or their designee to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections.

The Investigator and the Institution, if any, shall be jointly responsible for maintaining essential Study documents for the time and in the manner specified by current good clinical practice (GCP) guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. If the Investigator leaves an institution, then responsibility for maintaining Study records shall be determined in accordance with applicable regulations. If an investigator leaves an institution or otherwise changes addresses, he or she shall promptly notify the Sponsor or their designee of his or her new address.

The Site represents and warrants that neither it, nor any of its employees, agents or other persons performing the Study under its direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify the Sponsor or their designee immediately if any such investigation, disqualification, debarment, or ban occurs.

7) **Termination.**

The Sponsor may terminate this Agreement by giving prior written notice of fifteen (15) days in the event the Sponsor does not wish to continue the Study for any reason whatsoever or without assigning any reason. Notwithstanding any termination of this Agreement, Site will be entitled to payments due and payable till the date of termination. Upon termination, the Investigator will submit an up to date report on the Study conducted and return all confidential information of the Sponsor Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and the Sponsor shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the payment schedule.

Neither the Sponsor nor their designee shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to patient safety, the Sponsor may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

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8) **Claims and Disclaimers.**

The Site shall promptly notify the Sponsor or their designee in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Investigational Product and allow Sponsor to handle such claim (including settlement negotiations), and shall cooperate fully with Sponsor in its handling of the claim.

9) **Indemnification and Insurance.**

Sponsor shall indemnify, defend, and hold harmless institution from any damages and liability that arise out of the proper administration of the study device, study-required procedures, sponsor's use of the results, or sponsor's negligence or breach of the agreement.

The Sponsor expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product.

Neither the Sponsor nor their designee will be responsible for, and the Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any loss, claim, or demand arising from any injuries or damages resulting from the Site's negligence, failure to adhere to the Protocol, failure to obtain the informed consent, unauthorized warranties, breach of this Agreement or willful misconduct The Site shall maintain a commercially reasonable level of insurance, and, upon request, shall provide a certificate of insurance alternatively, if applicable insurance is provided by a governmental agency, the Site shall satisfy all requirements necessary to remain eligible for such governmental insurance during the Study.

10) **Subject Injury.**

The sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a study subject that is directly related to the administration of the investigational device or the proper performance of any other procedure, each in accordance with the protocol and the sponsor's written instructions to the institution (or to the extent that the sponsor's written instructions conflict with the protocol, the sponsor's written instructions to the institution only). The sponsor is not required under this section to provide compensation for (a) other injury- or illness-related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the institution nor the study subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the protocol or other misconduct or negligence, in each case by any agent or employee of the institution (including the study staff), (d) due to the natural progression of the investigational device and unrelated to the proper performance of any other procedure required by the protocol or sponsor's written instructions to the institution.

11) **Additional Contractual Provisions.**

The Site shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of the Sponsor or their designee. This Agreement, including these Terms and Conditions, constitutes the sole and complete agreement between the parties and replaces all other written and oral agreements relating to the Study. This Agreement shall be effective upon the date it is signed by all the parties and shall continue until completed or terminated.

No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the parties and their successors and assigns. The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of the Sponsor. The Sponsor may assign this Agreement to

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themselves or to a third party, and thereafter the Sponsor shall not have any obligations or liabilities under this Agreement, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee. The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement. This Agreement shall be interpreted under the laws of the state or province and country in which such Site conducts the Study.

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ATTACHMENT B

BUDGET AND PAYMENT SCHEDULE

Consideration

In consideration of Site conducting the Study and complying with all other terms of this Agreement, the Sponsor or their designee shall pay to the Site all inclusive sum of **Rs. 1,60,000 (Rs. One lakh sixty thousand)** per patient recruited for the Study. Payments made by the Sponsor or their designee will be subject to tax deduction at source unless an exemption certificate issued by an appropriate authority is provided to the Sponsor or their designee.

IRB/EC and additional Infrastructure/Equipment Payment:

IRB/EC and additional Infrastructure/Equipment costs will be reimbursed on a pass-through basis (upon receipt of a valid invoice) and are not included in the attached Budget. Any subsequent IRB/EC re-submissions or renewals, upon approval by the Sponsor, will be reimbursed upon receipt of appropriate documentation.

Payment Break-Up for Per Patient Grant (Rs. One lakh and sixty thousand) for the study and it will be remitted at the following instalments

Milestone	**Amount (INR)**
Implant (week 0)	1,00,000/
Follow up visit (1, 3, 6, 12, 18 & 24 months)	60,000/- (10,000 each visit)
Total per completed patient	**160,000/-**

"In addition to the payment of Rs. 160,000/-, Phoenix Cardiac will be providing the BACE device free of cost to the patient as well as all study related tests (ECG, ECHO, stress EKG, lab test etc.) and reasonable patient travel cost (excluding air travel) to site will be reimbursed within one month of submitting invoice, based on actual cost incurred. In addition, any cost requirement in regard to any device related SAE event will be directly borne by the Sponsor"

Site will also be provided additional funding for BACE implant related expenses such as surgery cost, hospitalization cost, etc, if required for the study.

Site has to provide supportive bills for the reimbursement.

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CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); and Dr. Veerappa Kothiwale, KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru nagar, Belgaum-590010, Karnataka, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Order shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20170199 entitled "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay

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Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within five (5) business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within five (5) business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: AMG 145 ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company under this Order.

3.2 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

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5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop .

5.2 Company-Provided Required Equipment. The parties agree that for this Order, Company will supply the following Required Equipment, which equipment is specified in Schedule A: Laptop ("**Company-Provided Required Equipment**").

The supply of the Company-Provided Required Equipment shall be part of the compensation for services rendered by Site under this Agreement. The current value of Company-Provided Required Equipment is identified in the Schedule A. At the expiration or earlier termination of the Agreement, Site will pay or Company will deduct from the final payment the then current value (as amortized) of such Company-Provided Required Equipment and ownership and title to such Company-Provided Required Equipment will transfer to Site. Company-Provided Required Equipment shall be transferred "as is".

5.3 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

5.4 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop .

5.5 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop .

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Dr. Veerappa A. Kothiwale "**Payee**"
TAX ID:	AEBPK3989H

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator

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is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement and this Order, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized

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and Research, BELAGAVI

representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

(signature)

By: Mansi Malkan

Title: Senior Country Manager

Date: 14th Feb 2018

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

(signature)

By: DR M.V. Jali
(print or type name)

Title: MD AND CE

Date: 21 Feb 2018

DR. VEERAPPA KOTHIWALE

(signature)

By: DR V.A. KOTHIWALE
(print or type name)

Title: PRINCIPAL INVESTIGATOR

Date: 19 Feb 2018

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

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Protocol Number	20170189
Site Number	30006
Investigator	Dr. Veerappa Kothiwale
Contract Number	
Number of Subjects	5
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 73,655	5	Subject(s)	INR 3,68,275
SCREEN FAILURES	INR 25,800	2	per Site	INR 51,600
ADDITIONAL SUBJECT FEES				INR 1,51,950
ADMINISTRATIVE FEES				INR 41,000
MAXIMUM CONTRACT TOTAL				**INR 6,12,825**

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs and laboratory costs.*

SUBJECT FEES (20% overheads)

VISIT TABLE: STUDY	Institution
Screening	INR 25,800
Day 1	INR 14,970
Week 4	INR 4,045
Week 8	INR 12,170
Week 12 (EOS)	INR 16,670
SUBJECT VISIT TABLE SUBTOTAL(S)	Institution
Maximum Per Subject Fee	INR 73,655
MAXIMUM PER SUBJECT FEE	**INR 73,655**

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel (800.00 INR) and meal (500.00 INR) reimbursement for each protocol required in-clinic visits

VISIT TABLE: SCREEN FAILURE	Institution
Screen Failure	INR 25,800
MAXIMUM SCREEN FAIL	**INR 25,800**

ADDITIONAL SUBJECT FEES (Institution)	UNIT COST	UNIT(S)	TYPE	TOTAL
Optional Visit (Week 2/ 6) - apheresis subjects only	INR 4,045	2	per Subject	INR 40,450
Chart review/ database search (per Hour- Study Coordinator)	INR 1,500	5	per Site	INR 7,500
Infrastructure Fee	INR 50,000	1	per Site	INR 50,000
ISD Line Rental (per month)	INR 1,500	36	per Site	INR 54,000
SUBTOTAL, ADDITIONAL SUBJECT FEES				**INR 1,51,950**

Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastucture.
Broadband ISD line charge will be provided on monthly basis after site initiation untill final monitoring visit.

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Institution)	UNIT COST	UNIT(S)	TYPE	TOTAL
Document Storage, Archving Total Cost for duration of site obligations	INR 41,000	1	per Site	INR 41,000
SUBTOTAL, ADMINISTRATIVE FEES				**INR 41,000**

Archival fee will be paid at the time of site close-out

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PAYMENT TERMS

Initial Payment	80,000.00 *Amgen will pay Institution this initial payment upon execution of the Agreement. In o to receive further funds towards Subject related costs, the amount earned must exceed this initi payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of '_____' (Tax id _____)
The EC for this study will be '_____' and the payment of the EC fees will be made in the favor of '_____'.

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors (including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale
2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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DEPT. OF STAMP & REGISTRATION INDIA Rs.0000100 PB6948

STAMP DUTY KARNATAKA

Sub Registrar Jayanagar, Bangalore

INVESTIGATOR CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" is made and entered into this 23rd day of Feb 2018 by and between

Biocad India Pvt. Ltd. Registered office address: #163/C, 3rd Cross, 3rd Phase, JP Nagar, Bangalore-560078, Karnataka, India., duly represented by Mr. Krishnamurthy Rao, Managing Director **(herein after referred to as "Biocad")**

AND

Dr. Shivakumar Patil (hereinafter referred to as the **"Principal Investigator"** or **"PI"**)

AND

KLES DR Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi, Karnataka - 590010, India (hereinafter referred to as the **"Institution."**)

And

Genesis Research Kolhapur (hereinafter referred to as the "SMO.")

in connection with conduct of clinical trial - "A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira® (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis" bearing the protocol/study ID: **BCD-057-2.**

PI, Institution and Biocad hereinafter are individually referred to as **"the Party"** and are jointly referred to as **"the Parties"**.

WHEREAS:

1. Sponsor is a pharmaceutical company responsible for execution of a clinical trial in **India.**

2. Biocad India is the Indian subsidiary of CJSC "BIOCAD" (Sponsor) which is a Russian biotechnology company, established in 2001. CJSC Biocad has both research and development and full cycle manufacturing facilities. Biocad India desires to engage the services of the PI to conduct/assist in this clinical trial ;

3. PI has the necessary qualification, training, skill and facilities to conduct the clinical trial and is desirous of rendering such services upon such terms and conditions as envisaged below.

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Clinical Trial Agreement-BCD-057-2
KLES Hospital and MRC,
Nehru nagar, Belagavi.
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1. **Provision of Services**

1.1 The services to be provided by the PI to Biocad are described in detail in the statement attached hereto and incorporated herein by references as **Exhibit A** (hereinafter referred to as **"the Proposal"**).

1.2 The Study will be conducted at the Institution under the supervision and direction of the Investigator, wherein Investigator shall control any individual performing any portion of the Study at the Institution. Site will carry out Study-related laboratory services and investigations as may be required for the Study.

1.3 The PI will conduct various activities with respect to the Clinical Trial (hereinafter referred to as **"activities"**) in accordance with the following:

- Responsibilities of PI (attached herewith as **Exhibit A**) and Protocol of Clinical trial as amended from time to time.
- Budget (attached herewith as **Exhibit B**)
- All applicable International Conference on Harmonisation (ICH) Good Clinical Practice (hereinafter referred to as **"GCP"**) guidelines.
- All relevant current Indian Regulations and guidelines implemented or advised by the Indian Laws.

1.4 Biocad will provide the PI with all the information, documents, and materials which, in Biocad's reasonable opinion, are required in order to carry out activities in a Clinical Trial.

1.5 Biocad transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.6 Biocad will appoint a representative (hereinafter referred to as the **"Clinical Research Associate (CRA)/Clinical Research Monitor (CRM)"**) to be authorised to monitor the activities of the Clinical Trial. The CRA/CRM will coordinate performance of Clinical Trial with the PI. All communications between Biocad and the PI regarding the conduct of Clinical Trial shall be addressed to or routed through the CRA/CRM. Biocad may, at its discretion, change the CRA/CRM during the course of Clinical Trial and inform the PI accordingly.

1.7 The PI will store copies of all data and records generated during the trial in accordance with local regulations, applicable GCP and as per the directions of Biocad.

This Agreement shall commence on the date of execution and shall continue till the date of payment of the last sum due hereunder or till the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

3. Termination and Consequences of Termination

Termination:

3.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

3.2 Either Party may terminate this Agreement by written notice of **forty five (45) days** to the other Party without assigning any reason thereof and **with no penalty on either side.**

3.3 Either Party may terminate this Agreement by written notice of **thirty (30) days** in advance issued by means of communication ensuring evidence of the date of receipt in case of a substantial breach by the other Party of the obligations arising out of this Agreement, provided the Party receiving such notice has neither remedied nor sufficiently explained for the breach within the period specified in the notice.

3.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 3.3 above.

3.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

3.6 Upon expiry or termination of this Agreement, Biocad shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Biocad to the PI under this Agreement exceed the project costs as set forth in the study Budget.

3.7 Upon expiry or termination of this Agreement, the PI shall, at Biocad' option, either immediately transfer to Biocad or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

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4. **Intellectual Property Ownership;**

4.1 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor (Biocad) which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor (Biocad).

4.2 The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the PI may publish data generated at their (own) site:

- only upon getting written approval from Sponsor and
- only after the first publication of such data by the Sponsor.

5. **Representations; Indemnification**

5.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

a. The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

b. All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

5.2 The PI will be covered by a professional indemnity of sufficient value as decided by Biocad, which shall be in force through out the term of this trial. However, this indemnity coverage does not cover any indemnity, liability or consequence arising out of or attributable to the negligence or willful misconduct of the PI.

6. **Conflict of Interests**

Site warrants that neither Institution nor Investigator has any conflict of interest that would affect the conduct of the Study. PI shall notify Biocad promptly and within twenty four (24) hours, if a conflict of interest arises during the term of this Agreement

7. **Payment**

7.1 The total fees and expenses payable by Biocad to the PI for the services set forth herein shall not exceed the Budget as per **Exhibit B.**

7.2 This study is non-negotiable and includes all costs associated with the conduct of the study, including pharmacy fees, laboratory fees, dry ice, procedure cost, study coordinator/investigator fees, patient payments, all overhead charges and administrative fees.

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Unless and otherwise agreed in writing, Biocad India shall make no payment for patients whom the investigator entered into the study in violation of protocol (i.e, the patient is not a qualified participant)

7.4 Biocad shall pay the **SMO** (Genesis Research) for same in accordance with the terms set forth herein after deducting there from any tax as applicable.

7.5 Payment shall be made by account payee Cheque / DD only.

8. Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

9. Arbitration

9.1 Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore.**

10. Force Majeure (Act of God)

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

11. Record Keeping

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

12. Review of Work, Audit

12.1 The PI shall agree and permit concerned Government Agency, Regulatory Body, Sponsor Representative to perform, during normal business hours, quality assurance audits of the work performed under this Agreement to determine that the services are being performed in accordance with the applicable study Protocol, Government Regulations and this Agreement. PI promptly shall correct any errors or deficiencies discovered during an audit, under intimation to Biocad.

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The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

14. Notices & Service of documents

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Biocad shall be addressed to:

Biocad India Pvt. Ltd.
#163/C, 3rd Cross,
3rd Phase, JP Nagar,
Bangalore-560078
Phone No. 080-41699773
Fax No. 080-41699773

All the correspondence/ notices to be sent by Biocad to PI shall be addressed to:

Dr. Shivakumar Patil
SMO, Second Floor , Sharavati ward
KLEs Dr Prabhakar Kore Hospital and MRC
Nehru Nagar, belagavi – 590010
Karnataka, India.

FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao **Managing Director** **Biocad India Private Limited**	**Genesis Research** **Mr. Satyjit Patil**	**Principal Investigator** **Dr. Shivakaumar Patil**	**Institute Head** **DR. M. V Jali**
Seal:	**Seal**	**Seal** Dr. Shivkumar Patil Consultant Dermatology KMC Reg No. 72067	**Seal:** Medical Director & Chief Exe KLES Dr. Prabhakar Kore Ho Medical Research Centre, BE
Witness	**Witness**	**Witness**	**Witness**

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Exhibit B: Proposal (Budget)

Budget and Payment Terms

1. All payments would be made only upon fulfilment of responsibilities by the PI as described in Exhibit A and the services provided by the PI as is described in the clinical trial protocol including its amendments.

2. Biocad India Pvt. Ltd. offers to pay the PI **Rs. 2,16,250*** which will be paid per subject as per Annexure I who completes full study (complete all study visits and procedures as required by the protocol)
   This payment is inclusive of all patient related cost as well as non patient related cost such as all Overhead expenses, completion of case report forms, audits, administrative costs (e.g. Internet, telephone, Fax, Xerox, prints etc.), Hospitalization and infusion charges, pharmacy fees and lab costs for testing {for example CBC, Biochemistry, ECG, ECHO, as per protocol requirement}, patient travel costs, including unscheduled visits as per protocol, study/site staff fees. (Subject to deductions as per point No.4 below):

   *The payment will be made as per the visits completed by the patient

3. For Screening Failure, Rs. 5000 will be paid to PI which includes institutional overhead charges.

   Reimbursement will be not be made for any additional testing, treatment or procedures not required by the protocol, unless such additional testing, treatment or procedures are pre-approved by the sponsor.

   Below laboratory tests should be performed at the institution/local laboratory.
   ECG, CBC, ESR & Biochemistry

   The costs for these are included in the budget. All other protocol specified laboratory examinations will be performed at sponsor identified central lab.

Terms of Payment:

- Payment will be made after verifying completed case report forms and completion of Resolution of Data Clarification Form/ Data queries raised by Data Management for that respective visit.
- In case the patient does not complete the milestone visits then the payment would be made as per the earliest milestone visit.
- Payment to the PI on the above milestones will be made on monthly basis only by a crossed A/C Payee Cheque in favour of Genesis Research. No payment shall be made in cash.
- The final payment will be subject to a final reconciliation, meaning after (i) all subjects have completed the study, and the database has locked, (ii) all study specific queries and issues (including data queries) has been satisfactorily

4. The following deductions will be made, if applicable:
   - Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.
   - Any capital expenses for the site incurred by Biocad on behalf of PI will be deducted from the fee payable to PI.

FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao **Managing Director** **Biocad India Private Limited**	**Genesis Research** **Mr. Satyjit Patil**	**Principal Investigator** **Dr. Shivakaumar Patil**	**Institute Head** **DR M. V Jali**
Seal: BIOCAD INDIA PVT. LTD. # 163/C, 3rd Cross, 3rd Phase, J.P. Nagar BANGALORE - 78	**Seal** GENESIS RESEARCH 4/22 Near Apoorva Hospital Jadhavwadi KOLHAPUR-416005	**Seal** Dr. Shivkumar Patil Consultant Dermatology KMC Reg No. 72067	**Seal:** Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI
Witness	**Witness**	**Witness**	**Witness**

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BUDGET SHEET

Treatment (visits 1 to 28); Final visit (29)

er of visit	Screening	1	1-1	1-2	1-3	1-4	1-5	1-6	2	3	4	5	6	7	8	9
py week	8	0							1	3	5	7	9	11	13	15
	-4-0	1	2	3	4	5	6	7	1	1	1	1	1	1	1	1
Grant	4000	1500	2000	2000	2000	2000	2000	2000	2000	1000	2500	1000	2500	2000	2000	2000
t 25%	800	500	400	400	400	400	400	400	400	400	500	400	500	400	400	400
Fees	1750	1000	750	750	750	750	750	750	750	750	1000	750	1000	750	1000	750
the extent and severity of psoriasis with PASI	X	X									X		X		X	
psoriasis severity with sPGA	X	X									X		X		X	
state the body surface area affected by psoriasis (BSA)	X	X									X		X		X	
psoriatic involvement of nails with NAPSI	X															
itch with visual analog scale (0-100 mm)	X															
DLQI questionnaire		X														
SF-36 questionnaire		X														
mple (pk biomarker)		500	500	500	500	500	500	500	500	500	500	500	500	500	500	500
ing Charge	300	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500
	300															
X-ray	500															
QuantiFERON-TB Gold test	3500															
plete blood count (Hemoglobin, Hematocrit, RBC, Leukocytes, lets, Neutrophils, Lymphocytes Eosinophils, ESR)	500										500		500		500	
d biochemistry (Glucose, ALT, AST, GGT, AP, Total bilirubin, atinine)	1800										1800		1800		1800	
e Analysis	250															
nancy test (Determination of hCG in urine)	100															
s for HIV, HCV, HBV, syphilis	2000															
nd Total	234250															

er of visit	9-1	9-2	9-3	9-4	9-5	9-6	10	10-1	10-2	10-3	11	12	13	14
py week	15	15	15	15	15	15	16	16	16	16	17	19	21	23
	2	3	4	5	6	7	1	2	3	4	1	1	1	1
Grant	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000
t 25%	400	400	400	400	400	400	400	400	400	400	400	400	400	400
Fees	750	750	750	750	750	750	1000	750	750	750	750	750	1000	750
the extent and severity of psoriasis with PASI							X						X	
psoriasis severity with sPGA							X						X	
state the body surface area affected by psoriasis (BSA)							X						X	
psoriatic involvement of nails with NAPSI							X							
itch with visual analog scale (0-100 mm)							X							
DLQI questionnaire							X							
SF-36 questionnaire							X							
mple (pk biomarker)	500	500	500	500	500	500	500	500	500	500	500	500	500	500
ing Charge	500	500	500	500	500	500	500	500	500	500	500	500	500	500
plete blood count							500						500	
d biochemistry							1800						1800	

er of visit	15	16	17	18	19	20	21	22	23	24	25	26	27	28	Final Visit 29
py week	25	27	29	31	33	35	37	39	41	43	45	47	49	51	55
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Grant	2000	2000	2000	2300	2100	1500	2000	1500	1500	1500	2000	1500	1500	1500	2000
t 25%	485	400	400	400	450	300	400	300	300	300	400	300	300	300	400
Fees	500	500	1000	500	500	500	500	500	500	500	500	500	500	500	500
the extent and severity of psoriasis with PASI			X		X		X				X				X
psoriasis severity with sPGA			X		X		X				X				X
state the body surface area affected by psoriasis (BSA)			X		X		X				X				X
psoriatic involvement of nails with NAPSI					X										X
itch with visual analog scale (0-100 mm)					X										X
DLQI questionnaire					X										X
SF-36 questionnaire					X										X
ing Charge	500	500	500	500	500	500	500	500	500	500	500	500	500	500	
	300														300
X-ray	500														500
QuantiFERON-TB Gold test	2500														2500
plete blood count	500						500						500		500
d biochemistry	1800						1800						1800		1800
e Analysis	250														250

rchival to be done at third party site,
P/SAI, as per actual,
IEC-MED as per actual, any
ficated above Rs. 5xx, prior
roval from Boxed India must be obtained,
INSTD 1 As per actual, any
ficated above Rs. 500, prior
roval from Boxed India must be obtained,
tional travel reimbursement: Rs 500 Visit
AT reimbursement on actual basis
hospitalization Rs 1500 per day- Hospitalization is not required, reimbursement only for out station patients on case to case basis

Medical ... Executive
KLES ... Hospital &
Med... ...re, BELAGAVI

Dr. Shiv... Consultant Dermatology

GENESIS RESEARCH 4/22 Near Apoorva Hospital Jadhavwadi

ATTESTED

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Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the _ day of _ 2018 between **1) Dr. Sameer Haveri ("Investigator"), Consultant Orthopedics at KLE's Dr. Prabhakar Kore Hospital** and **2) KLE's Dr. Prabhakar Kore Hospital ("Institution")** both having its address at **KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India 3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.; ("Reliance")**, with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

"Investigator", "Institution", "SMO" and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	RLS/OST/2016/05
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Prolia® in post-menopausal women with osteoporosis.
STUDY PRODUCT:	R-TPR-045 / Prolia®
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Sameer Haveri**
INSTITUTION/SITE:	**KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/OST/2016/05** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

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Regd. Office: Dhirubhai Ambani Life Sciences Centre, R-282, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai - 400 701, INDIA. • Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099. • Website: www.rellife.com
CIN : U24239MH2001PTC130654

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WHEREAS the Institution has engaged **Genesis Research** a Site Management Organization of **KLE's Dr. Prabhakar Kore Hospital & M.R.C.**, authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

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d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 Site Visits. The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product.

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

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c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 **New findings.** Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization:**

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

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including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

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time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:

i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or

ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

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iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

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11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or
(iii) any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or
(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.
c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and
d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and
e. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

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11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. **Financial Disclosure**. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee.

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Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

13. **Insurance**: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 **Solicitation of subject:** Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 **Press Releases:** Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 **Enquiries from media and financial analysts**: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 **Use of Name**: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 **Additional Contractual Provisions.**

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically

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authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 19 March 18

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Sameer Haveri

Title: Consultant Orthopedics

Date: _____

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: Dr. M. V. Jali.

Title: KLE's Dr. Prabhakar Kore Hospital & M.R.C.

Date: _____

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 26 Mar 2018

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	Genesis Research
PAYEE ADDRESS:	4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India
TAX ID NUMBER (PAN Number)	CQJPP0528D
GSTIN	27CQJPP0528D1ZX

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research** in Indian Rupees.

The Parties agree that the payee designated herein is the proper payee for this Agreement, and that payments under this Agreement will be made only to the designated payee ("Payee").

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

7) Start-up fee of Rs. 60000/- will be released by Reliance at the time of site initiation before screening first patient in the study.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: **RLS/OST/2016/05**

Investigational Product: R-TPR-045

Clinical Trial Budget		
	Project Name:	Denosumab
	Project Code	K069
	Name of PI	Dr. Sameer Haveri
		Unit Cost/Visit
Investigator fees		5,750
1	Principal Investigator	4,000
2	Clinical Research Coordinator	1,500
4	Phlebotomist (for PK and PD samples)	250
Patient related expenses		3,000
1	Travel reimbursement	500
2	Hospitalization charges	2,500
Administrative overhead-20% of Investigator Fee		800
Laboratory Testing Charges		
	Name	Cost
	Investigation	
1	Dexa Scan (BMD)	3,000
2	Spinal X-ray	500
3	12 lead ECG	300
4	Chest X Ray	500
5	X-ray (Maxillofacial region-Jaw)	500
	Study Start-up fee	60,000

- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study
- Hospitalization charges mentioned are for 24 hrs. Patient participating in PK will be hospitalized for 2 days.

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A.2 Per Visit Payment schedule:

Total study Budget/patient						
Visit	Sub visit..	Investigator fees	Laboratory Test	Patient related expenses	Administrative Overheads	TOTAL
Screening		5500	4800	500	800	11600
Day 1	0 hrs	5750	300	3000	800	9850
Day 3	48 hrs	250	0	3000	0	3250
Day 5		250	0	500	0	750
Day 7		250	0	500	0	750
Day 9		250	0	500	0	750
Day 11		250	0	500	0	750
Day 13		250	0	500	0	750
Day 15		250	0	500	0	750
Day 22		250	0	500	0	750
Day 29 (1M)		5750	0	500	800	7050
Day 43		250	0	500	0	750
Day 57		250	0	500	0	750
Day 85 (3M)		5750	0	500	800	7050
Day 113		250	0	500	0	750
Day 141		250	0	500	0	750
Day 183 (6M)		5750	4300	500	800	11350
9 Month		5750	0	500	800	7050
12 Month		5750	4300	0	800	10850
TOTAL		43000	13700	14000	5600	76300
					Total budget per subject excluding GST	76300
					cGST(9%) sGST(9%) iGST(18%)	90034

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Note:

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- # In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll 10 patients.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

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CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT is made on this 04 Day of Apr 2018 by and between,

Veeda Clinical Research Pvt. Ltd, an Indian Company having its principal place of business at Shivalik Plaza–B, Nr. I.I.M., Ambawadi, Ahmedabad – 380 015 Gujarat (hereinafter referred to as the "Veeda") which shall include its successors, assigns, representatives, affiliates, and subsidiaries,

And

Dr. Mahesh Kalloli ("Principal Investigator"), having its place of work at KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

And

KLES Dr.Prabhakar Kore Hospital and MRC ("Institution") having its principal place of business at Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

(Hereinafter referred to as the "Institution") which shall include its successors, assigns, representatives, affiliates, and subsidiaries.

WHEREAS, Veeda is a contract research organization contracted by Qilu Pharmaceutical Co., Ltd, No. 243 Gong Ye Bei Road, Jinan, Shandong Province, P.R., China - 250100 (herein after referred to as "Sponsor") to perform one or more of sponsor study related duties and functions for the Project No. 17-VIN-0855 entitled " A multicenter, open label, randomized, balanced, two treatment, three period, three sequence, reference replicate crossover, single dose, bioequivalence study of Capecitabine Tablets 500 mg of Qilu Pharmaceutical Co., Ltd, China in comparison with XELODA® (Capecitabine) Tablets 500 mg, Distributed by Genentech USA, Inc. following a single oral dose administration in adult cancer patients under fed condition."; and

WHEREAS, Principal Investigator is properly qualified and experienced and working at Institution and Principal Investigator has the authority and desire to conduct the Study at the Institution; and

WHEREAS, Institution has adequate infrastructure to conduct the Study and allowed Principal Investigator and Veeda to conduct the Study;

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

MUTAN NAGRIK SAHAKARI BANK LTD.

भारत STAMP DUTY SPLADH GUJARAT 1231 7208605

ATTESTED

Veeda Clinical Research Ahmedabad

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

1. DEFINITIONS

1.1 Definitions. As used in this Agreement, each capitalized term listed below shall have the meaning that is given after it:

- "Budget" means the detailed budget established for the Study, as detailed in Exhibit B, which is incorporated herein by reference.
- "CRF" or "Case Report Form" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Sponsor on each Subject.
- "Data" shall mean all information, reports, records, and documents generated under this Agreement, excluding subject medical records. Data shall be the sole and exclusive property of Sponsor and may be freely utilized by Sponsor and their representatives. Sponsor may freely assign its rights to and interests in any Data to a party of the Sponsor's choice.
- "Financial Disclosure Certification Form" means the financial disclosure certification attached as Exhibit B, to record compliance with 21 CFR Part 54 (U.S.).
- "ICH Guidelines" means the International Council for Harmonization, Harmonized Tripartite Guideline for Good Clinical Practice E6, 1996, or such successor provisions in force at the time of performance of the services.
- "IEC" means the Independent Ethics Committee/Institutional Ethics Committee ("IEC"), as the term is defined in ICH Guidelines and any other review board required by applicable law or ICH Guidelines.
- "Informed Consent" means a consent signed by or on behalf of a Subject which consent shall comply with the applicable local law and the regulations of the U.S. Department of Health and Human Services, its supporting agencies, the FDA and any other applicable regulatory agency governing informed consents including without limitation, Schedule Y, Section 4.8 of the ICH Guideline, 45 CFR §46.116(a), 21 CFR Part 50 and 21 CFR Part 812.
- "Protocol" means the document that specifies the clinical trial procedures, as developed by Sponsor applicable for the performance of a Study and any amendments thereto. Protocol shall be attached to this Agreement as Exhibit A.
- "Study Product" means Capecitabine tablets, 500 mg of Qilu Pharmaceutical Co., Ltd, No. 243 Gong Ye Bei Road, Jinan, Shandong Province, P.R., China - 250100 an investigational drug.
- "Subject" means an individual who meets all eligibility criteria, is properly consented and enrolled in the Study.

2. Scope

2.1 This Agreement allows the parties to specify distinct clinical study activities to be performed by Principal Investigator and Institution for the Study.

2.2 Conduct of Study Principal Investigator and Institution shall conduct the Study pursuant to the terms of this Agreement and in strict adherence to the Protocol, as the same may be amended from time to time in writing by Sponsor, and any other written instructions that may be provided from time to time to Principal Investigator by Sponsor. Prior to conducting the Study, the Principal Investigator shall review and understand the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the applicable Protocol, all of which are incorporated herein by reference.

2.3 Principal Investigator.

2.3.1 Principal Investigator shall be personally responsible for the conduct of the Study. If such personal services are not available for any reason, Veeda or Sponsor may terminate this Agreement immediately without any further financial obligation to Principal Investigator and / or Institution.

2.3.2 Principal Investigator agrees to return to Veeda any unearned or unaccounted for amounts paid by Veeda that exceed the amount to which Principal Investigator are entitled hereunder.

2.3.3 During the performance of the Clinical Trial and / or for a period of 15 years after termination of the agreement, the Principal Investigator is responsible for, but not be limited to, the following aspects:

a) Provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of Investigator(s) and sub-Investigator(s), confirmation of adequate site facilities, etc.);

b) Progress reporting (including recruitment figures) to Ethics Committee and Veeda on a regular basis;

c) Ensuring reasonable access by monitors, auditors and regulatory authorities to Principal Investigator and other project personnel, project facilities, original study materials, drug records, subject records, case reports, and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study-related monitoring, audit and inspection;

d) To allow any regulatory audit by DCGI or any applicable regulatory authorities within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Principal Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Veeda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure;

g) Maintenance of drug accountability records, study documents including study drug acknowledgment receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol; and

i) Storage of site file and all the trial related data for a period of 15 years after completion of the study without any additional cost / compensation / grants. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

j) The Principal Investigator is responsible for training and supervision of sub-Investigators and other site study team member on the procedures specified in the Protocol to ensure scientific, technical, and ethical conduct of the Clinical Trial. In case of any personnel changes, the Principal Investigator is responsible for notifying Veeda of such change in a timely manner.

2.3.4 The review of serious adverse events shall be undertaken by Veeda in close coordination with Principal Investigator. "Serious" as used in this section, refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. "Unexpected" as used in this section, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the Product, and conditions or developments occurring at a rate higher than shown by information previously submitted to an agency or other governmental agencies or encountered during clinical studies of the Product or, if applicable, conditions or developments not identified in the approved Product information circular, and includes any other meaning under applicable law.

2.3.5 Veeda shall have the right, to monitor or visit the Principle Investigator and audit the Trial with respect to the services provided hereunder with / without the Sponsor. Principal Investigator will cooperate with Veeda and the Sponsor and provide a current status of the trial.

2.3.6 The Principle Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. The Principle Investigator shall strictly adhere to the SAE reporting timeline as per the current regulations of licensing authority (DCGI), requirement of ICH GCP, current Schedule Y.

The investigator will be responsible to report any SAE to the licensing authority, Sponsor's representative, CRO representative and chairman of Ethics Committee within 24 hours of identifying the event as SAE.

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In case of SAE other than death the investigator will send the detailed report within 14 calendar days of SAE to the licensing authority, chairman of Ethics Committee where the SAE has occurred, and the head of the institution where the trial is being conducted.

In case of SAE of death the investigator will send the detailed report within 14 calendar days of SAE to the chairman of Ethics Committee, chairman of the expert committee constituted by the licensing authority with a copy to licensing authority and the head of the institution where the trial is being conducted.

Notwithstanding anything in this Agreement to the contrary, the Principal Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deem it necessary to protect the health of study participants, provided that Veeda is copied on such reports.

2.3.7 The Principle Investigator shall participate in teleconferences required by Veeda to update the study product information and resolve issues, if any.

2.3.8 The Principle Investigator and/or the Institution, Veeda and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records, including the patient's medical records. The Site Investigator File containing the essential documents and source data must be archived for at least fifteen (15) years following completion of the study at the Site or such other authorized facilities as agreed between Veeda, the Principle Investigator and the site. The Principle Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

2.3.9 In the event that the Principle Investigator is to destroy the Investigator Site File or source data, the Principle Investigator should inform Veeda prior to destruction to confirm it is acceptable for them to be destroyed.

2.3.10 Investigational Medicinal Product i.e. both unused and retention samples will be retained at the site after completion of the study for a desired period, as per USFDA/sponsor requirement and also as per the written instruction given by Veeda/Sponsor at free of cost. The samples will be retained for a period of at-least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at-least 5 years following the date of completion of bioavailability study in which the sample from which the reserve sample was obtained was used. Investigational Medicinal Product i.e. both unused and retention samples will continue to remain at the site unless further information is received from Veeda/Sponsor.

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2.3.11 Principal Investigator/ Institute will intimate to CRO and Sponsor about any inspection/s from any regulatory authorities for the study , within 48 business hours of their notification.

2.4 Compliance with Law. Principal Investigator and Institution represent that they shall comply with all applicable laws in performing its obligations under this Agreement. Principal Investigator will assume all those responsibilities assigned to principal investigators under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant ICH Guidelines and standards, and all applicable laws relating to the confidentiality, privacy and security of patient information. In furtherance of the foregoing obligation, Principal Investigator shall ensure that timely report is sent to the IEC for the progress and conduct of Study. Principal Investigator and Institution, as applicable, shall comply with the directives of the IEC respecting the conduct of the Study, and shall immediately notify Veeda and Sponsor to the extent any such directives vary from the Protocol. Principal Investigator shall obtain from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IEC and in conformity with local regulations and Sponsor's requirements therefore set forth in the Protocol.

2.5 Study Supplies. Veeda shall provide Principal Investigator with a sufficient quantity of Study Product to conduct the Study, as well as any other compounds, materials and information which the Protocol specifies. All such Study Product, compounds, materials and other information are and shall remain the sole property of Sponsor/Veeda. Principal Investigator and Institution, as applicable, shall ensure that the Study Product is stored and handled in accordance with protocol, all applicable laws in addition to any specific instructions from Sponsor and/or Veeda. Principal Investigator and Institution shall not use the Study Product past the labeled expiration date and shall not use the Study Product for any purpose other than the performance of the Protocol. In addition, upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the procedures to be provided by Veeda and/or Sponsor.

Veeda on behalf of sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

2.6 Delivery of Essential Documents and Reports. Principal Investigator shall provide to Veeda all Essential Documents (to be designated as such by Veeda) within two (2) weeks of Principal Investigator's receipt of IEC's written approval. If all Essential Documents have not been timely executed and received by Veeda, Veeda may terminate this Agreement immediately upon written notice. Principal Investigator shall submit written reports, as directed *by* Veeda and/or Sponsor, on the progress of the Study. Within thirty (30) days following the completion or premature termination of the Study, Principal Investigator shall furnish Veeda with the IEC report, notification as required by IEC on the Study prepared by the Principal Investigator, as well as all completed, used and unused CRFs not already delivered to Veeda, and all Data, reports and other information generated in relation to the Study, as well as all other materials and information

provided by Veeda and/or Sponsor, unless Veeda and/or Sponsor directs otherwise in writing.

2.7 Monitoring of Study. Principal Investigator and Institution shall permit Veeda and/or Veeda designee(s) including but not limited to Sponsor access to Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Study as well as to audit records, CRFs, Data and other information and documents relating to the Study, in order to verify Principal Investigator's compliance with their obligations herein. If any governmental entity should audit or inspect the Institution with respect to the Study, Principal Investigator and/or Institution shall provide Veeda and Sponsor with immediate notice and shall provide an opportunity for Sponsor or its designee to be present during such governmental audit.

2.8 Contract Research Organizations/vendors. Subject to Sponsor's approval, Veeda may retain one or more contract research organizations ("CRO")/vendor to assist them in managing and monitoring the Study. Principal Investigator and Institution acknowledge Veeda's right to assign or transfer, in whole or in part, without the consent of the Principal Investigator and Institution, any of its rights or obligations under this Agreement to any such CRO or vendors. The Principal Investigator and Institution shall permit such CROs/vendors to perform any or all of Veeda's obligations, or to exercise any or all of Veeda's rights, under this Agreement.

2.9 No Reimbursement for Sponsor Paid Drug or Services. Principal Investigator and Institution agrees that, if Study Product and/or other services are paid for or provided without charge by Sponsor or Veeda, Principal Investigator, Institution and/or any other vendor subcontracted or engaged by Principal Investigator or Institution shall not separately bill or seek reimbursement for such Study Product and/or services from any third party including, without limitation, the Subject, any private provider of Insurance or state program. Principal Investigator and Institution further agree that they shall accurately report receipt of such Study Product to any government or private insurance program, as may be required by law.

2.10 Financial Disclosure Certification. Principal Investigator or Institution, as applicable, shall ensure that any sub investigators connected with the Study, complete and return to Veeda and/or Sponsor the Financial Disclosure Certification Form prior to the initiation of the Study. Principal Investigator or Institution, as applicable, shall require any sub investigators to promptly notify Veeda and/or Sponsor of any change in the accuracy of the Financial Disclosure Certification Form during the term of Study and for one (1) year following completion of the Study. In addition, Principal Investigator or Institution, as applicable, shall comply with all applicable requirements of the National Institutes of Health and the Public Health Service regarding reporting and management of conflicts of interest.

3. COMPENSATION

3.1 Payment. Veeda shall pay Principal Investigator/Institution the amounts set forth in Exhibit B for Subjects properly enrolled, completed visits and CRFs completely and accurately returned to Veeda and/or Sponsor. All payments shall be payable in Indian Rupees and made within forty five

(45) days of receipt and approval of an invoice for Institution /Principal Investigator's services.

The parties hereto agree as follows:

a) Veeda will pay a sum for every complete and evaluable patient as defined in the payment schedule for "Per Patient Fee".

   The "Per Subject Fee" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

   - all study related activities such as conduct of visits and Source & CRF completion
   - time and effort of Principle Investigator and other site staff
   - study coordinator salary
   - all diagnostic tests and other investigations (ECG,Echo, X-ray Chest etc)
   - housing or hospital stay for patients including meals
   - Patient conveyance/compensation
   - miscellaneous (telephone, fax, courier, etc)
   - all overhead costs

b) A complete and evaluable patient is defined as follows:

   - all procedures must be performed according to the protocol
   - a patient will only be included according to the inclusion/exclusion criteria
   - all data are documented accurately, completely

c) All payments will be on a *pro rata* basis. For patients who do not complete (early termination, drop-out, etc), the payment schedule will be evaluated according to the number of days completed.

d) Invoice will be generated / requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs retrieval for completed visits). Invoice will be generated / requested according to milestone specified above. The final payment (20%) will be made at the time of site closeout visit or immediately after site close-out visit.

e) Any third parties designated by you (including Radiology, Local Laboratory, etc) will be managed and paid by you.

f) The Ethics Committee fee will be paid by Veeda, and is separate from the per-patient grant. Details of the payment are as mentioned below.

   - Name of Ethics Committee: **Institutional Ethics Committee, KLE University**
   - Relationship between the site/institution and Ethics committee: **Institutional Ethics Committee**

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- Ethics committee payee name: **Registrar KLE University.**
- Relationship between the Ethics committee and the Ethics committee payee name, if it is different from Ethics committee as mentioned in the SOP: **NA**
- PAN no. of the payee: **AABTK0881E**
- Ethics Committee Fees: **Rs. 88500/- (Excluding TDS)**

g) Screen failure patient's visit will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG,ECHO, X-ray Chest, and SAE or in case patient withdraw consent.

h) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

i) Patient conveyance will pay by Veeda, and is not included in per patient fees.

j) Veeda will manage SAE reimbursement for medical management expenses towards AE/SAE directly to the patient or LAR and SAE compensation payment directly to the patient / LAR with prior written approval from the sponsor and will get for reimbursement for those expenses.

k) Veeda will pay the Institution an upfront amount of INR 20,000/- once 1st patient is enrolled / randomized. This upfront amount will be adjusted form subsequent payment(s). In case site is not able to enroll any patients then Principle Investigator / Institute is liable and must return upfront amount immediately without any delay.

Details of Payee are:

Name of Payee: Genesis Research

PAN No. : CQJPP0528D

GSTIN No. : 27CQJPP0528D1ZX

Note: All the payments made to the payee are subject to Withholding Tax (Tax Deducted at Source (TDS)) as applicable from time to time and Veeda will deduct the tax at the time of making payments.

3.2 Disputed Payment. Principal Investigator/Institution agrees that in the event of a dispute regarding Sponsor's approval of documentation of supporting costs incurred under this Agreement, data and information resulting from Institution's (including Principal Investigator) participation in Study cannot be withheld by Institution's (including Principal Investigator) pending resolution of the dispute. Veeda and Principal Investigator/Institution agree to use reasonable efforts to resolve any disputes in a timely manner.

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3.3 Overpayment/Underpayment. If, at the date of Study termination, the total amount paid to Principal Investigator/Institution exceeds the amount to which Principal Investigator/Institution is entitled, Principal Investigator/Institution shall return the overpayment to Veeda within forty-five (45) days from the termination date. If, at the date of termination, the total amount paid to Principal Investigator/Institution is less than the amount to which Principal Investigator/Institution is entitled, Veeda shall pay the amount due to Principal Investigator/Institution within forty-five (45) days following termination of the Study, delivery to Veeda and/or Sponsor of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to Veeda of all items described in Section 2.7 above.

3.4 Commercially Reasonable Efforts. The Principle Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum Eligible Cases as soon as possible. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of 10 months however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more then specified.

Principal Investigator/Institution shall use reasonable efforts to complete enrollment of study subjects within two months (2) months after receiving a go ahead from the sponsor/veeda to enroll patients in the study. Veeda may terminate this Agreement upon written notice, if Principal Investigator/Institution is not able to enroll any patient for a month following Study initiation at their site and in that case, the Principal Investigator / Institution is responsible to refund the all amount paid till the date of termination of the agreement within 7 days from the date of intimation of termination of the agreement.

Allowed screen failure rate in the study is 20 %, hence the investigator should put in reasonable efforts to recruit eligible cases in the study.

3.5 Remittance of Payment. All payments to Principal Investigator/Institution and any other party as defined in this agreement made pursuant to this Agreement shall be made by Veeda and all study related payments will be made by cheque and sent to:

Trial Payee Address: KLES Dr. Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

3.6 Relationship of Parties. Veeda shall be responsible for all payments to Principal Investigator/Institution pursuant to this Agreement but such responsibility is subject to receipt of funds from Sponsor. Upon receipt of such funds by Veeda from Sponsor, Principal Investigator / Institution shall have no recourse against Sponsor or any of its subsidiaries or affiliates for Veeda's breach of its payment obligations to Investigator pursuant to this Agreement.

4. CONFIDENTIALITY

4.1 Confidentiality & Non-Use Obligation. During the Study's performance and for Five years (5) years thereafter, Institution, its employees, agents, and subcontractors (if any) and Principal

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Investigator shall not disclose Confidential Information (hereinafter defined) for any purpose other than as indicated in this Agreement without Sponsor's prior written consent.

4.2 Definition of Confidential Information. Subject to Principal Investigator's publication rights as set forth in Sections 6.1 and 6.2, " Confidential Information" shall include the Protocol, CRFs, Data, Study Product, and all materials and information in whatever form or medium (whether now known or in the future developed) and however communicated, be it by written, verbal, visual, machine readable form, or in the form of biological materials or samples, or in any other form, relating, directly or indirectly, to Sponsor and the Study disclosed to Principal Investigator and/or Institution by Sponsor or Veeda or developed by Principal Investigator or Institution as a result of conducting the Study. Confidential Information shall also include any confidential information obtained under a confidentiality agreement with a third party, which Sponsor is permitted to disclose to Principal Investigator and/or Institution.

4.3 Exceptions to Obligation of Confidentiality and Non-Use. Principal Investigator and Institution's obligation of confidentiality and non-use described in Section 4.1 applies to all Confidential Information, except any portion thereof which:

(i) Is known to Principal Investigator and Institution, its employees, agents, or subcontractors before receipt thereof under this Agreement, as evidenced by written records;

(ii) is disclosed to Principal Investigator and/or Institution, their employees, agents, or subcontractors after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner;

(iii) is or becomes part of the public domain through no fault of Principal Investigator or Institution , their employees, agents, or subcontractors; or

(iv) is independently developed by Principal Investigator or Institution, their employees, agents, or subcontractors, without reference to, use of, or disclosure of Confidential Information, as evidenced by written records.

4.4 Disclosure Required by Law. Nothing in this Agreement shall be construed to restrict Principal Investigator or Institution from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Institution and/or Principal Investigator shall timely inform Veeda and Sponsor and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, Institution and Principal Investigator shall permit Veeda and/or Sponsor to attempt to limit such disclosure by appropriate legal means.

4.5 Subject Confidentiality. The parties agree to abide by all applicable laws and regulations regarding Subject confidentiality. Principal Investigator is responsible for obtaining from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent in a form approved in writing by the IEC and in conformity with Sponsor's guidelines. Before requesting an

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individual's consent to participate in clinical trial the Principal Investigator must provide the individual with the trial information in a language that is non- technical and understandable by the study subjects and the same shall be recorded as per local regulatory requirement.

This is in case requirement of Audio visual recording. During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept confidential; and that no details about identity of said subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the subject concerned, or someone authorized on their behalf, and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the trial. Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the Investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial.

The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

5. INTELLECTUAL PROPERTY

5.1 Inventions. All inventions whether or not patentable, discoveries, techniques, ideas, trade secrets, new uses, improvements, processes, compounds, products, and all other works that are conceived or reduced to practice during the course of performing the Clinical Trial by Principal Investigator and Institution (including but not limited to their employees, agents and/or any other vendor subcontracted or engaged by Principal Investigator or Institution) ("Intellectual Property") shall be promptly disclosed to Veeda and Sponsor and shall be the sole property of Sponsor; provided however, that Principal Investigator and Institution will have a fully-paid-up, royalty-free, perpetual, nonexclusive right without the right to sublicense, to make, have made, and use any Intellectual Property created here under for its own internal, noncommercial research, noncommercial patient care, and academic purposes. Principal Investigator and Institution agree, upon Sponsor's written request and at Sponsor's expense, to execute such documents and to take such other reasonable actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name covering any Intellectual Property. Sponsor may freely assign its rights to and interests in any Intellectual Property to a party of the Sponsor's choice.

6. PUBLICATIONS

6.1 General procedures. If Principal Investigator prepares any presentation or publication, Principal Investigator is to provide Sponsor with a draft of the same for Sponsor's review and comment at least sixty (60) days prior to publication or presentation so that Sponsor may ascertain whether any Intellectual Property or other patentable Subject matter or Confidential Information

are disclosed therein. Sponsor shall return comments to Principal Investigator within thirty (30) days after receipt of the draft presentation or publication ("Review Period"). In addition, Principal Investigator shall delay any proposed publication/presentation an additional sixty (60) days in addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. TERM & TERMINATION

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

8. INDEMNIFICATION

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments

thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement. Notwithstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program.

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Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and Institution will notify Veeda promptly in writing to the extent possible within two (2) business days if either of these certifications needs to be amended in light of new information or if Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If to Veeda:

Veeda Clinical Research Pvt. Ltd.

Address: Shivalik Plaza –A, 2nd floor, Nr. I.I.M., Ambawadi, Ahmedabad 380 015.

Attention: Dr. E. Venu Madhav

Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principal Investigator:

Name: Dr. Mahesh Kalloli

Address: KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

Attention:

Phone : +918312470400
Fax: +918312493099

If to Institution:

Name: Dr M.V. Jali

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Designation: MD and CE

Address: KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

Attention:

Phone: +918312470400
Fax: +918312493099

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veeda and Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services here under, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement.

11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be

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Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10 Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11 Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

11.12 PI/Institute will be responsible for facilitating the availability of site level Phlebotomist dedicated for this study throughout the study duration.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madhav
Title: COO

Date: 05 Apr 2018

For, Principal Investigator

Name: Dr. Mahesh Kalloli
Title: Principle Investigator

Date: 14 Apr 2018

For, Institute

Name : Dr. M. V. Jali
Title: MD and CE

Date: 28 APR 2018

Witness:

Name: Snehal Wandre

Contact Details: 9657279369

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SCHEDULE "A"

PROTOCOL

TITLE:

"A multicenter, open label, randomized, balanced, two treatment, three period, three sequence, reference replicate crossover, single dose, bioequivalence study of Capecitabine Tablets 500 mg of Qilu Pharmaceutical Co., Ltd, China in comparison with XELODA® (Capecitabine) Tablets 500 mg, Distributed by Genentech USA, Inc. following a single oral dose administration in adult cancer patients under fed condition."

SCHEDULE "B"

STUDY BUDGET

All defined terms shall have the same meaning attributed to them in the Agreement unless otherwise defined herein.

Institution/Principal Investigator will be paid based upon the number of Subjects properly enrolled and the visits completed by the Subjects as legibly, completely and accurately recorded in the CRFs.

Screen failure will be paid an amount of 5,000 INR respectively.

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Vega Clinical Research Ahmedabad

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a) Trial Budget

Visit	Screening	Day 0	Day 1	Day 2	Day 3	EOS	Sub-total
Study Team Grant							
Principal Investigator Grant	4000	4000	6000	6000	6000	4000	30000
Study coordinator grant	2000	1500	1500	1500	1500	2000	10000
Phlebotomy Charges for Central lab sample collection	200					200	400
Phlebotomy Charges for PK sample*			1500	1500	1500		4500
Study Assessment Grant							
Local lab ANC and Platelet Count		200**					200
Heamoglobin in local lab			100	100	100		300
International Normalized Ratio	700					700	1400
Urine Pregnancy Test		150					150
Urine Drug screen test & Alcohol Breath Analyzer	150	150					300
ECG	500					500	1000
2D Echo	1500					1500	3000
X-Ray Chest	500						500
Stationary, Phone, Courier and Fax charge	200	100	200	200	200	200	1100
Hospitalization & Meal Charges		2500	2500	2500	2500		10000
Institutional Overhead (20%)	1200	1100	1500	1500	1500	1200	8000
Total	10950	9700	13300	13300	13300	10300	70850
IGST (18%)	1971	1746	2394	2394	2394	1854	12753
Total							83603

Visit	Screening	Day 0	Day 1	Day 2	Day 3	EOS	Sub-total

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Patient Compensation	1000	1000	1000	1000	1000	1000	6000
* Phlebotomy charges for PK sampling will be paid only if site phlebotomist is used. ** Prior to dosing on day 0 (can be done after last dose in period I & at local laboratory).							
Note: Per Patient budget inclusive of all applicable taxes. Archival fee is 20,000/- Rs. for 5 years.							

Taxes:

- All payments shall be made to the Principle Investigator / Institution / any other payee party as defined in the agreement, after deducting of withholding tax (TDS) as applicable from time to time as per the Income tax act. The TDS certificates for the withholding tax will be provided at the end of the financial year.

- Patient compensation will be treated as a reimbursement and TDS will be not deducted from the patient compensation subject to production of original bills and supporting documents (signed by patient) without any mark up by the Principle Investigator and Institution.

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SCHEDULE "A"

PROTOCOL

TITLE:

"A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection (2mg/mL) of 10mL or 25mL of Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL or 50 mg/25 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, administered in female patients with ovarian cancer whose disease has progressed or recurred after platinum based chemotherapy under fed condition."

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT is made on this 11 of Apr 2018 by and between, **Veeda Clinical Research Pvt. Ltd,** an Indian Company having its principal place of business at Shivalik Plaza–B, Nr. I.I.M., Ambawadi, Ahmedabad – 380 015 Gujarat (hereinafter referred to as the "Veeda") which shall include its successors, assigns, representatives, affiliates, and subsidiaries,

And

Dr. Maheshkumar Kalloli ("Principal Investigator"), having its place of work at KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi, 590010, Karnataka , India.

And

KLES **Dr. Prabhakar Kore** Hospital and MRC ("Institution") having its principal place of business at Nehru Nagar, Belagavi, 590010, Karnataka , India

And

KLES **Dr. Prabhakar Kore** Hospital and MRC (hereinafter referred to as the "Institution") which shall include its successors, assigns, representatives, affiliates, and subsidiaries.

WHEREAS, Veeda is a contract research organization contracted by Mylan Laboratories Limited. Bilekahalli, Bannerghatta Road, Bangalore 560076, India(herein after referred to as "Sponsor") to perform one or more of sponsor study related duties and functions for the Project No. 13-VIN-443 entitled "A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 20mg/10mLof Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, administered in female patients with ovarian cancer whose disease has progressed or recurred after platinum based chemotherapy under fed condition.and

WHEREAS, Principal Investigator is properly qualified and experienced and working at Institution and Principal Investigator has the authority and desire to conduct the Study at the Institution; and

WHEREAS, Institution has adequate infrastructure to conduct the Study and allowed Principal Investigator and Veeda to conduct the Study;

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1. DEFINITIONS

1.1 Definitions. As used in this Agreement, each capitalized term listed below shall have the meaning that is given after it:

- "Budget" means the detailed budget established for the Study, as detailed in Exhibit B, which is incorporated herein by reference.
- "CRF" or "Case Report Form" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Sponsor on each Subject.
- "Data" shall mean all information, reports, records, and documents generated under this Agreement, excluding subject medical records. Data shall be the sole and exclusive property of Sponsor and may be freely utilized by Sponsor and their representatives.Sponsor may freely assign its rights to and interests in any Data to a party of the Sponsor's choice.
- "Financial Disclosure Certification Form" means the financial disclosure certification attached as Exhibit B, to record compliance with 21 CFR Part 54 (U.S.).
- "ICH Guidelines" means the International Conference on Harmonization, Harmonized

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Tripartite Guideline for Good Clinical Practice E6 (R1), 1996, or such successor provisions in force at the time of performance of the services.

- "IEC" means the Independent Ethics Committee/Institutional Ethics Commitee ("IEC"), as the term is defined in ICH Guidelines and any other review board required by applicable law or ICH Guidelines.
- "Informed Consent" means a consent signed by or on behalf of a Subject which consent shall comply with the applicable local law and the regulations of the U.S. Department of Health and Human Services, its supporting agencies, the FDA and any other applicable regulatory agency governing informed consents including without limitation, Schedule Y, Section 4.8 of the ICH Guideline, 45 CFR §46.116(a), 21 CFR Part 50 and 21 CFR Part 812.
- "Protocol" means the document that specifies the clinical trial procedures, as developed by Sponsor applicable for the performance of a Study and any amendments thereto. Protocol shall be attached to this Agreement as Exhibit A.
- "Study Product" means Doxorubicin Hydrochloride Liposome Injection (2mg/mL) of 10mL or 25mL of Mylan Laboratories Limited, India an investigational drug.
- "Subject" means an individual who meets all eligibility criteria, is properly consented and enrolled in the Study.

2. Scope

2.1 This Agreement allows the parties to specify distinct clinical study activities to be performed by Principal Investigator and Institution for the Study.

2.2 Conduct of StudyPrincipal Investigator and Institution shall conduct the Study pursuant to the terms of this Agreement and in strict adherence to the Protocol, as the same may be amended from time to time in writing by Sponsor, and any other written instructions that may be provided from time to time to Principal Investigator by Sponsor. Prior to conducting the Study, the Principal Investigator shall review and understand the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the applicable Protocol, all of which are incorporated herein by reference.

2.3 Principal Investigator.

2.3.1 Principal Investigator shall be personally responsible for the conduct of the Study. If such personal services are not available for any reason, Veeda or Sponsor may terminate this Agreement immediately without any further financial obligation to Principal Investigator and / or Institution.

2.3.2 Principal Investigator agrees to return to Veeda any unearned or unaccounted for amounts paid by Veeda that exceed the amount to which Principal Investigator are entitled hereunder.

2.3.3 During the performance of the Clinical Trial and / or for a period of 15 years after termination of the agreement, the Principal Investigator is responsible for, but not be limited to, the following aspects:

a) Provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of Investigator(s) and sub-Investigator(s), confirmation of adequate site facilities, etc.);
b) Progress reporting (including recruitment figures) to Ethics Committee and Veeda on a regular basis;
c) Ensuring reasonable access by monitors, auditors and regulatory authorities to Principal Investigator and other project personnel, project facilities, original study materials, drug records, subject records, case reports, and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study-related monitoring, audit and inspection;
d) To allow any regulatory audit by DCGI or any applicable regulatory authorities within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Principal Investigator is to submit any

information to such regulatory authorities agencies, such submissions shall not be made without Veeda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure;

g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol; and

i) Storage of site file and all the trial related data for a period of 15 years after completion of the study without any additional cost / compensation / grants. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorised third party location.

j) The Principal Investigator is responsible for training and supervision of Sub-Investigators and other site study team member on the procedures specified in the Protocol to ensure scientific, technical, and ethical conduct of the Clinical Trial. In case of any personnel changes, the Principal Investigator is responsible for notifying Veeda of such change in a timely manner.

2.3.4 The review of serious adverse events shall be undertaken by Veeda in close coordination with Principal Investigator. "Serious" as used in this section, refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. "Unexpected" as used in this section, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the Product, and conditions or developments occurring at a rate higher than shown by information previously submitted to an agency or other governmental agencies or encountered during clinical studies of the Product or, if applicable, conditions or developments not identified in the approved Product information circular, and includes any other meaning under applicable law.

2.3.5 Veeda shall have the right, to monitor or visit the Principle Investigator and audit the Trial with respect to the services provided hereunder with / without the Sponsor. Principal Investigator will cooperate with Veeda and the Sponsor and provide a current status of the trial.

2.3.6 The Principle Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. The Principle Investigator shall strictly adhere to the SAE reporting timeline as per the current regulations of licensing authority (DCGi), requirement of ICH GCP, current Schedule Y.

The investigator will be responsible to report any SAE to the licensing authority, Sponsor's representative, CRO representative and chairman of Ethics Committee within 24 hours of identifying the event as SAE.

In case of SAE other than death the investigator will send the detailed report within 14 calendar days of SAE to the licensing authority, chairman of Ethics Committee where the SAE has occurred, and the head of the institution where the trial is being conducted.

In case of SAE of death the investigator will send the detailed report within 14 calendar days of SAE to the chairman of Ethics Committee, chairman of the expert committee constituted by the licensing authority with a copy to licensing authority and the head of the institution where the trial is being conducted.

Notwithstanding anything in this Agreement to the contrary, the Principal Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deem it necessary to protect the health of study participants, provided that Veeda is copied on such reports.

2.3.7 The Principle Investigator shall participate in teleconferences required by Veeda to update the study product information and resolve issues, if any.

2.3.8 The Principle Investigator and/or the Institution, Veeda and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records, including the patient's medical records. The Site Investigator File containing the essential documents and source data must be archived for at least fifteen (15) years following completion of the study at the Site or such other authorised facilities as agreed between Veeda, the Principle Investigator and the site. The Principle Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorised third party location.

2.3.9 In the event that the Principle Investigator is to destroy the Investigator Site File or source data, the Principle Investigator should inform Veeda prior to destruction to confirm it is acceptable for them to be destroyed.

2.3.10 Site will store, use and dispose any Study Drug and any placebo or comparator drug in strict accordance with the Protocol and any applicable laws, rules and regulations, and will not use the Study drug for purposes other than conducting the Study. Site will maintain appropriate controls to ensure proper handling of any such drugs. Site will return unused Study Drug and any other Study-related drugs in accordance with reasonable instructions that will be provided by Veeda/Sponsor. Site will be supplied with the Study Drug by Sponsor free of charge.

2.4 Compliance with Law. Principal Investigator and Institution represent that they shall comply with all applicable laws in performing its obligations under this Agreement. Principal Investigator will assume all those responsibilities assigned to principal investigators under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant ICH Guidelines and standards, and all applicable laws relating to the confidentiality, privacy and security of patient information. In furtherance of the foregoing obligation, Principal Investigator shall ensure that timely report is sent to the IEC for the progress and conduct of Study. Principal Investigator and Institution, as applicable, shall comply with the directives of the IEC respecting the conduct of the Study, and shall immediately notify Veeda and Sponsor to the extent any such directives vary from the Protocol. Principal Investigator shall obtain from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IEC and in conformity with local regulations and Sponsor's requirements therefore set forth in the Protocol.

2.5 Study Supplies. Veeda shall provide Principal Investigator with a sufficient quantity of Study Product to conduct the Study, as well as any other compounds, materials and information which the Protocol specifies. All such Study Product, compounds, materials and other information are and shall remain the sole property of Sponsor/Veeda. Principal Investigator and Institution, as applicable, shall ensure that the Study Product is stored and handled in accordance with protocol, all applicable laws in addition to any specific instructions from Sponsor and/or Veeda. Principal Investigator and Institution shall not use the Study Product past the labeled expiration date and shall not use the Study Product for any purpose other than the performance of the Protocol. In addition, upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the procedures to be provided by Veeda and/or Sponsor.

Veeda on behalf of sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

2.6 Delivery of Essential Documents and Reports. Principal Investigator shall provide to Veeda all Essential Documents (to be designated as such by Veeda) within two (2) weeks of Principal Investigator's receipt of IEC's written approval. If all Essential Documents have not been timely executed and received by Veeda, Veeda may terminate this Agreement immediately upon written

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notice. Principal Investigator shall submit written reports, as directed *by*Veeda and/or Sponsor, on the progress of the Study. Within thirty (30) days following the completion or premature termination of the Study, Principal Investigator shall furnish Veeda with the IEC report, notification as required by IEC on the Study prepared by the Principal Investigator, as well as all completed, used and unused CRFs not already delivered to Veeda, and all Data, reports and other information generated in relation to the Study, as well as all other materials and information provided by Veeda and/or Sponsor, unless Veeda and/or Sponsor directs otherwise in writing.

2.7 Monitoring of Study. Principal Investigator and Institution shall permit Veeda and/or Veeda designee(s) including but not limited to Sponsor access to Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Study as well as to audit records, CRFs, Data and other information and documents relating to the Study, in order to verify Principal Investigator's compliance with their obligations herein. If any governmental entity should audit or inspect the Institution with respect to the Study, Principal Investigator and/or Institution shall provide Veeda and Sponsor with immediate notice and shall provide an opportunity for Sponsor or its designee to be present during such governmental audit.

2.8 Contract Research Organizations/vendors. Subject to Sponsor's approval, Veeda may retain one or more contract research organizations ("CRO")/vendor to assist them in managing and monitoring the Study. Principal Investigator and Institution acknowledge Veeda's right to assign or transfer, in whole or in part, without the consent of the Principal Investigator and Institution, any of its rights or obligations under this Agreement to any such CRO or vendors. The Principal Investigator and Institution shall permit such CROs/vendors to perform any or all of Veeda's obligations, or to exercise any or all of Veeda's rights, under this Agreement.

2.9 No Reimbursement for Sponsor Paid Drug or Services. Principal Investigatorand Institution agrees that, if Study Product and/or other services are paid for or provided without charge by Sponsor or Veeda, Principal Investigator, Institution and/or any other vendor subcontracted or engaged by Principal Investigator or Institution shall not separately bill or seek reimbursement for such Study Product and/or services from any third party including, without limitation, the Subject, any private provider of Insurance or state program. Principal Investigator and Institution further agree that they shall accurately report receipt of such Study Product to any government or private insurance program, as may be required by law.

2.10 Financial Disclosure Certification. Principal Investigator or Institution, as applicable, shall ensure that any sub investigators connected with the Study, complete and return to Veeda and/or Sponsor the Financial Disclosure Certification Form prior to the initiation of the Study. Principal Investigator or Institution, as applicable, shall require any sub investigators to promptly notify Veeda and/or Sponsor of any change in the accuracy of the Financial Disclosure Certification Form during the term of Study and for one (1) year following completion of the Study. In addition, Principal Investigator or Institution, as applicable, shall comply with all applicable requirements of the National Institutes of Health and the Public Health Service regarding reporting and management of conflicts of interest.

3. COMPENSATION

3.1 Payment. Veeda shall pay Principal Investigator/Institution the amounts set forth in Exhibit B for Subjects properly enrolled, completed visits and CRFs completely and accurately returned to Veeda and/or Sponsor. All payments shall be payable in Indian Rupees and made within forty five (45) days of receipt and approval of an invoice for Institution /Principal Investigator's services.

The parties hereto agree as follows:

a) Veeda will pay a sum for every complete and evaluable patient as defined in the payment schedule for "Per Patient Fee".
The "Per Subject Fee" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and CRF completion
- time and effort of Principle Investigator and other site staff
- study coordinator salary
- all diagnostic tests and other investigations (ECG, 2D ECHO, X-ray Chest etc)
- housing or hospital stay for patients including meals
- Patient conveyance/compensation
- miscellaneous (telephone, fax, courier, etc)
- all overhead costs

b) A complete and evaluable patient is defined as follows:
   - all procedures must be performed according to the protocol
   - a patient will only be included according to the inclusion/exclusion criteria
   - all data are documented accurately, completely

c) All payments will be on a *pro rata* basis. For patients who do not complete (early termination, drop-out, etc), the payment schedule will be evaluated according to the number of days completed.

d) Invoice will be generated / requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs retrieval for completed visits). Invoice will be generated / requested according to milestone specified above. The final payment (20%) will be made at the time of site closeout visit or immediately after site close-out visit.

e) Any third parties designated by you (including Radiology, Local Laboratory, etc) will be managed and paid by you.

f) The Ethics Committee fee will be paid by Veeda, and is separate from the per-patient grant. Details of the payment are as mentioned below.
   - Name of Ethics Committee: **Institutional Ethics Committee, KLE University**
   - Relationship between the site/institution and Ethics committee: Institute Operated only
   - Ethics committee payee name: **Registrar KLE University**
   - Relationship between the Ethics committee and the Ethics committee payee name, if it is different from Ethics committee as mentioned in the SOP: **Institute Payee only the payment will be to the Institute only because the Clinical Trials payment will be managed separately.**
   - PAN no. of the payee: AABTK0881E
   - GST No. – 27CQJPP0528D1ZX
   - Ethics Committee Fees: **Rs. 88,500/- (Excluding TDS and Including GST)**

g) Screen failure patient's visit will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, 2D ECHO, X-ray Chest, SAE or in case patient withdrew consent.

h) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

i) Patient conveyance will pay by Veeda, and is not included in per patient fees.

j) Veeda will pay the Institution an upfront amount of INR 20,000/- once 1st patient is enrolled / randomized. This upfront amount will be adjusted form subsequent payment(s). In case site is not able to enrol any patients then Principle Investigator / Institute is liable and must return upfront amount immediately without any delay.

Details of Payee are:

Name of Payee: Genesis Research
PAN No. : CQJPP0528D
GSTIN No. : 27CQJPP0528D1ZX

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Note: All the payments made to the payee are subject to Withholding Tax (Tax Deducted at Source (TDS)) as applicable from time to time and Veeda will deduct the tax at the time of making payments.

3.2 Disputed Payment. Principal Investigator/Institution agrees that in the event of a dispute regarding Sponsor's approval of documentation of supporting costs incurred under this Agreement, data and information resulting from Institution's (including Principal Investigator) participation in Study cannot be withheld by Institution's (including Principal Investigator) pending resolution of the dispute. Veeda and Principal Investigator/Institution agree to use reasonable efforts to resolve any disputes in a timely manner.

3.3 Overpayment/Underpayment. If, at the date of Study termination, the total amount paid to Principal Investigator/Institution exceeds the amount to which Principal Investigator/Institution is entitled, Principal Investigator/Institution shall return the overpayment to Veeda within forty-five (45) days from the termination date. If, at the date of termination, the total amount paid to Principal Investigator/Institution is less than the amount to which Principal Investigator/Institution is entitled, Veeda shall pay the amount due to Principal Investigator/Institution within forty-five (45) days following termination of the Study, delivery to Veeda and/or Sponsor of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to Veeda of all items described in Section 2.7 above.

3.4 Commercially Reasonable Efforts.

The Principle Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum Eligible Cases as soon as possible. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of 3 months however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more then specified.

Principal Investigator/Institution shall use reasonable efforts to complete enrollment of study subjects within two months (2) months after receiving a go ahead from the sponsor/veeda to enroll patients in the study. Veeda may terminate this Agreement upon written notice, if Principal Investigator/Institution is not able to enroll any patient for a month following Study initiation at their site and in that case, the Principal Investigator / Institution is responsible to refund the all amount paid till the date of termination of the agreement within 7 days from the date of intimation of termination of the agreement.

Allowed screen failure rate in the study is 10 %, hence the investigator should put in reasonable efforts to recruit eligible cases in the study.

3.5 Remittance of Payment. All payments to Principal Investigator/Institution and any other party as defined in this agreement made pursuant to this Agreement shall be made by Veeda and all study related payments will be made by cheque and sent to:

Trial Payee Address: KLES Dr Prabhakar Kore Hospital and MRC , Nehru Nagar, belagavi – 590010, Karnataka , India.

3.6 Relationship of Parties. Veeda shall be responsible for all payments to Principal Investigator/Institution pursuant to this Agreement but such responsibility is subject to receipt of funds from Sponsor. Upon receipt of such funds by Veeda from Sponsor, Principal Investigator / Institution shall have no recourse against Sponsor or any of its subsidiaries or affiliates for Veeda's breach of its payment obligations to Investigator pursuant to this Agreement.

4. CONFIDENTIALITY

4.1 Confidentiality & Non-Use Obligation. During the Study's performance and for Five years (5) years thereafter, Institution, its employees, agents, and subcontractors (if any) and Principal Investigator shall not disclose Confidential Information (hereinafter defined) for any purpose other than as indicated in this Agreement without Sponsor's prior written consent.

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4.2 Definition of Confidential Information. Subject to Principal Investigator's publication rights as set forth in Sections 6.1 and 6.2, " Confidential Information" shall include the Protocol, CRFs, Data, Study Product, and all materials and information in whatever form or medium (whether now known or in the future developed) and however communicated, be it by written, verbal, visual, machine readable form, or in the form of biological materials or samples, or in any other form, relating, directly or indirectly, to Sponsor and the Study disclosed to Principal Investigator and/or Institution by Sponsor or Veeda or developed by Principal Investigator or Institution as a result of conducting the Study. Confidential Information shall also include any confidential information obtained under a confidentiality agreement with a third party, which Sponsor is permitted to disclose to Principal Investigator and/or Institution.

4.3 Exceptions to Obligation of Confidentiality and Non-Use. Principal Investigator and Institution's obligation of confidentiality and non-use described in Section 4.1 applies to all Confidential Information, except any portion thereof which:

(i) Is known to Principal Investigator and Institution, its employees, agents, or subcontractors before receipt thereof under this Agreement, as evidenced by written records;

(ii) is disclosed to Principal Investigator and/or Institution, their employees, agents, or subcontractors after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner;

(iii) is or becomes part of the public domain through no fault of Principal Investigator or Institution , their employees, agents, or subcontractors; or

(iv) is independently developed by Principal Investigator or Institution, their employees, agents, or subcontractors, without reference to, use of, or disclosure of Confidential Information, as evidenced by written records.

4.4 Disclosure Required by Law. Nothing in this Agreement shall be construed to restrict Principal Investigator or Institution from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Institution and/or Principal Investigator shall timely inform Veeda and Sponsor and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, Institution and Principal Investigator shall permit Veeda and/or Sponsor to attempt to limit such disclosure by appropriate legal means.

4.5 Subject Confidentiality. The parties agree to abide by all applicable laws and regulations regarding Subject confidentiality. Principal Investigator is responsible for obtaining from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent in a form approved in writing by the IEC and in conformity with Sponsor's guidelines. Before requesting an individual's consent to participate in clinical trial the Principal Investigator must provide the individual with the trial information in a language that is non- technical and understandable by the study subjects and the same shall be recorded through audio-visual means, if applicable.

During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept confidential; and that no details about identity of said subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the subject concerned, or someone authorised on their behalf, and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the trial.

The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the Investigator, if applicable. Such consent may be taken orally.

5. INTELLECTUAL PROPERTY

5.1 Inventions. All inventions whether or not patentable, discoveries, techniques, ideas, trade secrets, new uses, improvements, processes, compounds, products, and all other works that are conceived or reduced to practice during the course of performing the Clinical Trial by Principal Investigator and Institution (including but not limited to their employees, agents and/or any other vendor subcontracted or engaged by Principal Investigator or Institution) ("Intellectual Property") shall be promptly disclosed to Veeda and Sponsor and shall be the sole property of Sponsor; provided however, that Principal Investigator and Institution will have a fully-paid-up, royalty-free, perpetual, nonexclusive right without the right to sublicense, to make, have made, and use any Intellectual Property created hereunder for its own internal, noncommercial research, noncommercial patient care, and academic purposes. Principal Investigator and Institution agree, upon Sponsor's written request and at Sponsor's expense, to execute such documents and to take such other reasonable actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name covering any Intellectual Property. Sponsor may freely assign its rights to and interests in any Intellectual Property to a party of the Sponsor's choice.

6. PUBLICATIONS

6.1 General procedures. If Principal Investigator prepares any presentation or publication, Principal Investigator is to provide Sponsor with a draft of the same for Sponsor's review and comment at least sixty (60) days prior to publication or presentation so that Sponsor may ascertain whether any Intellectual Property or other patentable Subject matter or Confidential Information are disclosed therein. Sponsor shall return comments to Principal Investigator within thirty (30) days after receipt of the draft presentation or publication ("Review Period"). In addition, Principal Investigator shall delay any proposed publication/presentation an additional sixty (60) days in addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. TERM & TERMINATION

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

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8. INDEMNIFICATION

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement.Not withstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program. Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and

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Institution will notify Veeda promptly in writing to the extent possible within two (2) business days if either of these certifications needs to be amended in light of new information or if Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If toVeeda:

Veeda Clinical Research Pvt. Ltd.
Address: Shivalik Plaza –A, 2nd floor, Nr. I.I.M., Ambawadi, Ahmedabad 380 015.
Attention: Dr. E. VenuMadhav
Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principal Investigator:
Name: Dr Maheshkumar Kalloli
Address: KLES Dr Prabhakar Kore Hospital and MRC
Nehru Nagar, Belagavi -590010, Karnataka, India
Attention: Dr Deepak Tumari
Phone: + 9964403640
Fax: +918312493099

If to Institution:
Name:Dr M.V. Jali
Designation: **MD and CE**
Address: KLES Dr Prabhakar Kore Hospital and MRC
Nehru Nagar, Belagavi -590010, Karnataka, India
Attention: Dr Deepak Tumari
Phone: + 9964403640
Fax: +918312493099

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veedaand Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services hereunder, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement.

Veeda Clinical Research Ahmedabad
ATTESTED

Prof. Dr. V.A KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10 Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11 Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madav
Title: COO
Date: 12 Apr 2018

Veeda Clinical Research Ahmedabad

For, Principle Investigator

Name: Dr. Maheshkumar Kalloli
Title: Principle Investigator
Date: 18 APR 2018

For, Institute

Name : Dr M.V.Jali
Title: MD and CE
Date: 26 APR 2018

Witness:

Name : PRASHANT BANDUNI
Contact Details : 8497880864

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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Visit	Visit 1 (Screening)	Visit 2 (Day 0/28)	Visit 3 (Day 7/24)	Visit 4 (Day 2/30)	Visit 5 (Day 3/31)	Visit 6 (Day 4/32)	Visit 7 (Day 5/33)	Visit 8 (Day 8/36)	Visit 9 (Day 11/39)	Visit 10 (Day 15/43)	Visit 11 (Day 28-35)	EOS	Study total
Study Team Grant													
Principal Investigator	6000	8000	8000	5500	5500	5500	5500	5500	5500	5500	5500	6000	72000
Study coordinator grant	2000	3500	3500	2000	2000	2000	2000	2000	2000	2000	2000	2000	27000
Study Nurse grant	500	500	500	500	500	500	500	500	500	500	500	500	6000
Phlebotomy Charges	500	200	4000*	300*	300*	300*	300*	300*	300*	300*	500	500	8400
Dietician Charges			1000										1000
Study Assessment Grant													
ICF process audio video recording	1200												1200
Urine Pregnancy Test, Urine cotinine, UDS	300	600											900
ECG	500										500	500	1500
X-ray	500												500
2D-ECHO	1500										1500	1500	4500
CBC with platelet at		600											600
APTT, PT-INR at local	600											600	1200
Stationary, Phone, Courier and Fax charge	400	200	500	200	200	200	200	200	200	200	200	300	3000
Hospitalization & Meal Charges charges for (2000 INR/ night)		2500	2500	2500	2500	2500							12500
Sub-total	**14000**	**16100**	**16000**	**10700**	**10700**	**10700**	**8200**	**8200**	**8200**	**8200**	**10700**	**11900**	**140300**
Institutional Overhead	**2800**	**3220**	**3200**	**2140**	**2140**	**2140**	**1640**	**1640**	**1640**	**1640**	**2140**	**2380**	**26720**
Total													**167020**
Patient Compensation	1000	2000	2000	1000	1000	1000	1000	1000	1000	1000	1000	1000	**14000**

* Phlebotomy charges for PK sampling will be paid only if site phlebotomist is used.

ATTESTED

Prof. Dr. V. [illegible]
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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SCHEDULE "B"

STUDY BUDGET

All defined terms shall have the same meaning attributed to them in the Agreement unless otherwise defined herein.

Institution/Principal Investigator will be paid based upon the number of Subjects properly enrolled and the visits completed by the Subjects as legibly, completely and accurately recorded in the CRFs.

Screen failure will be paid an amount of 5,000 INR respectively.

a) **Trial Budget:**

Taxes:

- All payments shall be made to the Principle Investigator / Institution / any other payee party as defined in the agreement, after deducting of withholding tax (TDS) as applicable from time to time as per the Income tax act. The TDS certificates for the withholding tax will be provided at the end of the financial year.

- Patient compensation will be treated as a reimbursement and TDS will be not deducted from the patient compensation subject to production of original bills and supporting documents (signed by patient) without any mark up by the Principle Investigator and Institution.

Ecron Clinical Research Ahmedabad

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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CORPUSCLES
Relevant ngHealthcare

AlfaCorpusclesPvt.Ltd

Office . 25/36, First Floor,
East Patel Nagar,
New Delhi -110008, India.
T.+91 11 43572941

Factory . L-149, Sector-1,
Bawana Industrial Estate,
New Delhi -110039, India.
T.+91 9811105289

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (CTA) is made in Delhi between Alfa Corpuscles Pvt Ltd, (also called the Company) 25/36, First Floor, East Patel Nagar, New Delhi 110008, India, represented by Dr. Atul Sardana, Head of Research and Product Development (also called as the Principal Investigator)

AND

Dr. Dnyanesh Morkar - (M.B.B.S, M. D, D.N.B.), (also called as Site Investigator) at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India

AND

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India (also called as Site).

AND

GDD Experts (India) Pvt. Ltd., (also called as SMO) Ground Floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India

Whereas Alfa Corpuscles wishes to conduct the following Indian Council of Medical Research (ICMR) (also called as the Sponsor) Funded Study with Dr. Dnyanesh Morkar as the Site Investigator at the above mentioned site:

1. Title: A Multicenter, open label, prospective study to evaluate safety and effectiveness of the safety syringe developed by Alfa Corpuscles Pvt. Ltd. India in patients who require dose administration by parenteral route using the syringe or phlebotomy procedure as a part of their treatment/ diagnosis

Protocol No.: 14-VIN-527

The objectives of the trial are to assess the effectiveness of safety syringe by evaluating usage, acceptance, perception of safety & other determining factors on which consumers base their decision for routine usage and to monitor the safety of the patients

It is hereby agreed by and between Alfa Corpuscles Pvt. Ltd. And the Site Investigator here to as follows:

1. The site of the trial would be KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India.
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Site investigator will be paid a sum of INR 750 / Syringe Use
4. A total of 333 subjects will be enrolled in the study for the Safety Syringe Arm and a total of 333 subjects will be enrolled in the study for the Comparator Syringe Arm
5. The payments will be done to the designated Payee on a Monthly basis to the following account details

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Registrar
KLE Academy of Higher Education and Research, BELAGAVI

- Payee Name / Name of the account holder: GDD Experts India Pvt. Ltd.
- Bank Name: AXIS BANK LTD
- Account Number: 910020034162231
- Bank Address: AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
- IFSC Code: UTIB0000048
- PAN Card Number: AADCG0363Q
- GST Number: 27AADCG0363Q1ZA

Role and responsibilities of Dr. Dnyanesh Morkar (Site Investigator)

1) To conduct the above referenced Study as the Site Investigator.
2) The Site investigator has to complete 133 intramuscular administrations, 133 intravenous administrations, 17 subcutaneous administrations and 50 phlebotomy procedures using the safety syringe. The number of patients can be increased by Alfa Corpuscles Pvt Ltd.
3) The recruitment period for the study is three months. The Company expects a total of 333 syringes data from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Site investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The Site Investigator should be available and permit monitoring and auditing by the representative of the Company/ Principal Investigator, and inspection by the appropriate authority
6) The Site Investigator should ensure that all persons assisting with the study are adequately informed about the protocol; the investigational product(s), and their trial-related duties and functions.
7) The Site Investigator should conduct the trial in compliance with the protocol agreed to by the Sponsor and Principal Investigator and, which was given approval/favourable opinion by the IEC.
8) The Site Investigator should not implement any deviation from, or changes of the protocol without agreement by the Principal Investigator and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects,
9) The Site Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

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10) All serious adverse events (SAEs) should be reported immediately to the Principal Investigator/ Company except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
11) The Principal Investigator would like to have intermittent report every as and when required during the course of the study.
12) The Principal Investigator would like to have all the documents of investigations such as completed case record forms, completed informed consent, investigation reports (i.e. source documents)-if any, trial report - with signature and stamp of the investigator.
13) Contents of the report during the clinical trial should be kept confidential and not be revealed to any other company in India or outside India without written permission from the Principal Investigator.
14) The data obtained during the trial will not be published by the Site Investigator. The Company and the Principal Investigator will have the right to use this for publication of a research paper.
15) In case the Site Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Site Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Alfa Corpuscles Pvt Ltd.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of GDD Experts:

GDD Experts will be assisting PI in Trial Management, Project Management and Quality Management.

Role and responsibilities of Alfa Corpuscles Pvt Ltd (Company) and Principal Investigator

1) The Company and Principal Investigator is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The Company and Principal Investigator is responsible for securing agreement from all involved parties including Site Investigator and Site etc.
3) The Company and Principal Investigator is responsible to provide appropriately qualified individuals to, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
4) The Company and Principal Investigator will be responsible for providing insurance to the study subjects and Indemnification to the entire site if required.

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Prof. Dr. V.A.KOTHIWALE
Registrar
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5) The Company and Principal Investigator will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

6) The Company and Principal Investigator will be responsible for monitoring and auditing of the study.

It is hereby agreed by and between Alfa Corpuscles Pvt. Ltd.(Company) and Dr. Honey Susan Raju (Site Investigator) to all the terms and conditions as mentioned in this agreement

Acknowledged and agreed on behalf of Alfa Corpuscles Pvt. Ltd, 25/36, First Floor, East Patel Nagar, New Delhi 110008, India

By:

ALFA CORPUSCLES PVT. LTD. New Delhi

Name: Dr. Atul Sardana
Title: Head of Research & Product Development
Date: ~~21/09/2017~~ 23/04/2018

Acknowledged and agreed on behalf of KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India

By:

Name: Dr. M. V. Jali
Title: Medical Director
Date: 23/6/18

Acknowledged and agreed by Site Investigator at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India

By:

Name: Dr. Dnyanesh Morkar
Title: Site Investigator
Date: 20 Jun 2018

Acknowledged and agreed on behalf of GDD Experts India Pvt. Ltd., Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India

By:

Name: Dr. Vinod Gyanchandani
Title: Head- Clinical Operations
Date: 07/May/2018

ATTESTED

Prof. Dr V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the 29 day of May 2018 between **1) Dr. Rekha Mudhol ("Investigator"), Consultant Ophthalmologist,** at KLES Dr.Prabhakar Kore hospital and Medical research Centre **2) KLES Dr.Prabhakar Kore hospital and Medical research Centre ("Institution")** having its office at Neharu Nagar, Belagavi-590010, Karnataka, India, **3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.**; through its **Clinical Research Business ("Reliance")**, with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

"Investigator", "Institution", "SMO" and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	RLS/OPT/2016/06
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration.
STUDY PRODUCT:	R-TPR-024 / Lucentis®
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Rekha Mudhol**
INSTITUTION/SITE:	**KLES Dr.Prabhakar Kore hospital and Medical research Centre, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Clinical Research Business of Reliance Life Sciences is involved in clinical trials management and related clinical development activities;

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/OPT/2016/06** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

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KLE Academy of Higher Education and Research, BELAGAVI

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WHEREAS the Institution has engaged **Genesis Research ("SMO")** a Site Management Organization of **KLES Dr.Prabhakar Kore hospital and Medical research Centre** authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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Prof. Dr. V. A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

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Registrar
KLE Academy of Higher Education
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d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 Site Visits. The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product.

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 **New findings.** Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization:**

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
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including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly ~~by the Sponsor~~ or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

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transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator, SMO and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator, SMO and Institution during the course of the that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to the Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification number(s) and / or addresses.

The Investigator shall retain the Records of the Study, including either the original of all volunteer consent forms, for the longer of:

(i) two (2) years after the date of the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region for the Study Product in the indication being investigated.

(ii) two (2) years after the Investigator is notified by Sponsor that the clinical development of the Study Product has been formally discontinued; and

(iii) as may be required under the applicable Indian laws and regulations.

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or SMO or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution//Investigator, and Institution//Investigator shall comply with Sponsor's directions.

7. **Publication.** The results of the Study including all obtained data will be the property of the Sponsor. The Investigator, SMO and Institution should not publish or communicate the data in public without written authorisation by the Reliance Unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of the Sponsor. The Investigator and /or Institution and/or SMO may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by the Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action; however, any delay in publication shall not exceed one hundred and twenty (120) days after Investigator takes the requested action.

8. **Subject Injury Reimbursement**

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor agrees to reimburse Institution and/or Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Trial Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 122 DAB of Drugs and Cosmetics Rules 1945 in case of Trial Subject's injury and/or death. Institution and Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Institution, SMO and Investigator further agree to promptly notify Sponsor of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

9. **Inspection and Debarment.**

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from

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time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:
   i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or
   ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

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iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

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11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or

(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or

(iii) any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,

(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or

(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;

b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.

c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and

d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and

e. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. **Financial Disclosure**. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

13. **Insurance**: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 **Solicitation of subject:** Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 **Press Releases:** Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 **Enquiries from media and financial analysts**: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 **Use of Name**: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 **Additional Contractual Provisions.**

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

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16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and

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Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 09 May 2018

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Rekha Mudhol

Title: Consultant Ophthalmology

Date: 11 May 2018

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: DR M.V. Jali

Title: MD & CE

Date: 29 May 2018

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 10 may 2018

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research ("SMO")**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	**Genesis Research, kolhapur**
PAYEE ADDRESS:	**4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**CQJPP0528D**
GSTIN	**27CQJPP0528D1ZX**

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research ("SMO")** in Indian Rupees.

The Parties agree that the payee designated herein is the proper payee for this Agreement, and that payments under this Agreement will be made only to the designated payee ("Payee").

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory

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documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

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Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: **RLS/OPT/2016/06**
Investigational Product: R-TPR-024

A.2 Per Visit Payment schedule:

Clinical Trial Budget		
	Project Name:	Ranibizumab
	Project Code	K071
	Name of PI	Dr. Rekha Mudhol
		Unit Cost/Visit
Investigator fees		6,250
1	Principal Investigator	4,000
2	Clinical Research Coordinator	2,000
3	Phlebotomist (for PK and PD samples)	250
Patient related expenses		3,100
1	Travel reimbursement	500
2	Hospitalization charges	2,500
3	Consumables	100
Administrative overhead-25%		1,000
Laboratory Testing Charges		3,500
	Name	Cost
	Investigation	
1	Ocular Examination Including visual acuity Test	500
2	Slit Lamp Examination	500
3	Tonometry	500
4	Optical coherence tomography	2,000

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Total Budget						
Visit	**Sub visit**	**Investigator fees**	**Laboratory Test**	**Patient related expenses**	**Administrative Overheads**	**TOTAL**
Screening		6250	3500	500	1000	**11250**
Day 0	0 hrs	6250	1500	3000	1000	**11750**
	6hrs	250	0	0	0	**250**
	12hrs	250	0	0	0	**250**
	24 hrs	250	0	0	0	**250**
Day 2	48 hrs	250	0	600	0	**850**
Day 7		6750	1500	500	1000	**9750**
Day 30 (W4)	(predose third dosing)	6000	3500	500	1000	**11000**
Week 8		6000	3500	500	1000	**11000**
Week 12		6000	3500	500	1000	**11000**
Week 16		6250	3500	500	1000	**11250**
Week 20		6000	3500	500	1000	**11000**
Week 24		6250	3500	500	1000	**11250**
TOTAL		**56750**	**27500**	**7600**	**9000**	**100850**
					Total budget per subject excluding GST	**100850**
					IGST(18%)	**18153**
					Grand Total Per Subject	**119003**

Note:-

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- # In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll minimum 10 patients.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).
- Advance payment of Rs. 50000/- will be paid after site initiation visit for this study at this center.

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Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

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Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the 29 day of May 2018 between 1) **Dr. Rekha Mudhol ("Investigator"), Consultant Ophthalmologist,** at KLES Dr.Prabhakar Kore hospital and Medical research Centre 2) **KLES Dr.Prabhakar Kore hospital and Medical research Centre ("Institution")** having its office at Neharu Nagar, Belagavi-590010, Karnataka, India, **3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.**; through its **Clinical Research Business ("Reliance")**, with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

"Investigator", "Institution", "SMO" and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	RLS/OPT/2016/06
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration.
STUDY PRODUCT:	R-TPR-024 / Lucentis®
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Rekha Mudhol**
INSTITUTION/SITE:	**KLES Dr.Prabhakar Kore hospital and Medical research Centre, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Clinical Research Business of Reliance Life Sciences is involved in clinical trials management and related clinical development activities;

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/OPT/2016/06** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

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Regd. Office: Dhirubhai Ambani Life Sciences Centre, R-282, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai - 400 701, INDIA. • Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099. • Website: www.rellife.com
CIN: U24239MH2001PTC130654

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WHEREAS the Institution has engaged **Genesis Research ("SMO")** a Site Management Organization of **KLES Dr.Prabhakar Kore hospital and Medical research Centre** authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 **Site Visits.** The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 **Study Product.**

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

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c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 **New findings.** Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization:**

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

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including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

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transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator, SMO and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator, SMO and Institution during the course of the that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to the Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification number(s) and / or addresses.

The Investigator shall retain the Records of the Study, including either the original of all volunteer consent forms, for the longer of:

(i) two (2) years after the date of the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region for the Study Product in the indication being investigated.

(ii) two (2) years after the Investigator is notified by Sponsor that the clinical development of the Study Product has been formally discontinued; and

(iii) as may be required under the applicable Indian laws and regulations.

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or SMO or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution//Investigator, and Institution//Investigator shall comply with Sponsor's directions.

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7. **Publication.** The results of the Study including all obtained data will be the property of the Sponsor. The Investigator, SMO and Institution should not publish or communicate the data in public without written authorisation by the Reliance Unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of the Sponsor. The Investigator and /or Institution and/or SMO may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by the Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action; however, any delay in publication shall not exceed one hundred and twenty (120) days after Investigator takes the requested action.

8. **Subject Injury Reimbursement**

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor agrees to reimburse Institution and/or Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Trial Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 122 DAB of Drugs and Cosmetics Rules 1945 in case of Trial Subject's injury and/or death. Institution and Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Institution, SMO and Investigator further agree to promptly notify Sponsor of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

9. **Inspection and Debarment.**

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from

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time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and, Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:

i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or

ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

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iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or
(iii) any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or
(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.
c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and
d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and
e. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

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11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. **Financial Disclosure**. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

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13. **Insurance**: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 Solicitation of subject: Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 Press Releases: Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 Enquiries from media and financial analysts: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 Use of Name: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 Additional Contractual Provisions.

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

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16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and

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Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 09 May 2018

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Rekha Mudhol

Title: Consultant Ophthalmology

Date: 11 May 2018

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: DR M.V. Jali

Title: MD & CE

Date: 29 May 2018

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 10 may 2018

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Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated **"Genesis Research ("SMO")"** as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	**Genesis Research, kolhapur**
PAYEE ADDRESS:	**4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**CQJPP0528D**
GSTIN	**27CQJPP0528D1ZX**

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research ("SMO")** in Indian Rupees.

The Parties agree that the payee designated herein is the proper payee for this Agreement, and that payments under this Agreement will be made only to the designated payee ("Payee").

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory

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documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: **RLS/OPT/2016/06**
Investigational Product: R-TPR-024

A.2 Per Visit Payment schedule:

Clinical Trial Budget		
	Project Name:	Ranibizumab
	Project Code	K071
	Name of PI	Dr. Rekha Mudhol
		Unit Cost/Visit
Investigator fees		6,250
1	Principal Investigator	4,000
2	Clinical Research Coordinator	2,000
3	Phlebotomist (for PK and PD samples)	250
Patient related expenses		3,100
1	Travel reimbursement	500
2	Hospitalization charges	2,500
3	Consumables	100
Administrative overhead-25%		1,000
Laboratory Testing Charges		3,500
	Name	Cost
	Investigation	
1	Ocular Examination Including visual acuity Test	500
2	Slit Lamp Examination	500
3	Tonometry	500
4	Optical coherence tomography	2,000

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Total Budget						
Visit	Sub visit	Investigator fees	Laboratory Test	Patient related expenses	Administrative Overheads	TOTAL
Screening		6250	3500	500	1000	11250
Day 0	0 hrs	6250	1500	3000	1000	11750
	6hrs	250	0	0	0	250
	12hrs	250	0	0	0	250
	24 hrs	250	0	0	0	250
Day 2	48 hrs	250	0	600	0	850
Day 7		6750	1500	500	1000	9750
Day 30 (W4)	(predose third dosing)	6000	3500	500	1000	11000
Week 8		6000	3500	500	1000	11000
Week 12		6000	3500	500	1000	11000
Week 16		6250	3500	500	1000	11250
Week 20		6000	3500	500	1000	11000
Week 24		6250	3500	500	1000	11250
TOTAL		56750	27500	7600	9000	100850
					Total budget per subject excluding GST	100850
					IGST(18%)	18153
					Grand Total Per Subject	119003

Note:-

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- # In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll minimum 10 patients.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).
- Advance payment of Rs. 50000/- will be paid after site initiation visit for this study at this center.

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Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

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CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement (**"Agreement"**) is made by and among:

- **KLE's Dr. Prabhakar Kore Hospital and Medical Research Center**, having a place of business at Nehru Nagar, Belagavi- 590010, Karnataka, India (the "**Institution**"), and;
- **Dr. Archana Uppin**, having a place of business at KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belagavi- 590010, Karnataka, India (the "**Investigator**"), and;
- **CMS Clinical Research Pvt. Ltd.**, having a place of business at Inox Towers, Plot No.- 17, Sector 16, A Film City, Noida- 201301, Uttar Pradesh, India (the "**Research Company**"), and;
- **IQVIA RDS (India) Private Limited** (formerly Quintiles Research (India) Private Limited), having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India ("**IQVIA**").

Each a "**Party**" and together the "**Parties**".

Protocol Number:	LRP-YLB113-2017-001
Protocol Title:	Randomized, Controlled Open Label Clinical Study to Compare the Impact of Single Transition from Enbrel® Auto-Injector (AI) to YLB113 AI on Safety, PK and Compare Usability of Both AIs in Patients with Active Rheumatoid Arthritis (RA).
Protocol Date:	19 July 2018
Sponsor:	Lupin Ltd.
Country where Site is Conducting Study	India
Investigator:	Dr. Archana Uppin *"an employee of Institution"*
Key Enrollment Date:	**100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 2.9 "Key Enrollment Date" below)**
IRB/IEC	Name: Institutional Ethics Committee Address: KLES University, Nehru Nagar, Belagavi- 590010, Karnataka, India Name of the Chairperson: Dr. Subarna Roy Telephone Number : +91 8312475477/78

RECITALS:

WHEREAS, **IQVIA** is providing clinical research organisation services to Sponsor under a separate agreement between **IQVIA** and **Sponsor** (**"Service Agreement"**). Under the said **Service Agreement**, **IQVIA's** services inter alia include monitoring of the **Study** and contracting with clinical research sites;

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WHEREAS, the **Institution** and **Investigator** (hereinafter jointly the "**Site**") are willing to conduct the **Study** and **IQVIA** requests the **Site** to undertake such **Study**, subject to terms and conditions as stated **Agreement**, the **Protocol** and the **Applicable Law**.

NOW THEREFORE, it is hereby agreed by and among the **Parties** as follows:

1. **DEFINITIONS**

The following additional definitions shall apply to this **Agreement:**

1.1 **Applicable Law**: means any statute, law, regulation, ordinance, rule, judgment, injunction, order, decree, ruling, licence, permit, consent, approval, directive, agreement, guideline, policy or restriction, or any requirement or decision or interpretative, legislative or administrative action of, or determination by, any **Authority** (as defined below) having jurisdiction over the matter in question, or otherwise applicable to the **Parties**, whether in effect as of the date of this **Agreement** or at any time thereafter.

1.2 **Authority**: means any constitutional, judicial, governmental, quasi-governmental, legislative, statutory, quasi-judicial, departmental, regulatory or public body constituted by any statute or ordinance or by a court of competent jurisdiction, or any authority within the territory or elsewhere, having jurisdiction over the **Parties**.

1.3 **Protocol**: the clinical protocol referenced above as it may be modified from time to time by the **Sponsor** (defined below).

1.4 **Case Report Form** or **CRF**: case report form (paper or electronic) to be used by **Site** to record all of the **Protocol**-required information to be reported to **Sponsor** on each **Study Subject** (defined below).

1.5 **Study**: the clinical trial that is to be performed in accordance with this **Agreement** and the **Protocol** for purposes of gathering information about the compound/medical device identified in the **Protocol**.

1.6 **Study Subject**: an individual who participates in the **Study**, either as a recipient of the **Investigational Product** (defined below) or as a control.

1.7 **Study Staff**: the individuals involved in conducting the **Study** under the direction of the **Investigator**.

1.8 **Investigational Product**: the compound/medical device identified in the **Protocol** that is being tested in the **Study**.

1.9 **Good Clinical Practices** or **GCPs**: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

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1.10 **Sponsor**: the sponsor of the **Study**.

1.11 **Medical Records**: the **Study Subjects'** primary medical records kept by the **Institution** on behalf of the **Investigator,** including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

1.12 **Study Data**: all records and reports, other than **Medical Records**, collected or created pursuant to or prepared in connection with the **Study** including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to **Sponsor** pursuant to the **Protocol** and all records regarding inventories and dispositions of all **Investigational Product**.

1.13 **Government Official**: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

1.14 **Item(s) of Value:** should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

1.15 **Dual Capacity**: the capacity of holding a **Government Official** position and being a party to this **Agreement**.

1.16 **Regulatory Approval:** means any and all permits, consents, grants, approvals, authorizations, licenses, waivers, exemptions, concessions, sanctions, permissions, registrations, certificates, agreements, orders, declarations, filings, reports or notices of, with or to any **Authority** pursuant to **Applicable Law**.

1.17 **MCI Regulations:** Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

2. CONDUCT OF THE STUDY

2.1 Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that **Site** and **Study Staff** shall perform the **Study** at **Institution** in strict accordance with this **Agreement**, the **Protocol**, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs, MCI Regulations, and state and local tax and finance regulations. **Site** and **Study Staff** acknowledge that **IQVIA** and **Sponsor**, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

2.2 Obligations of Site.

Site shall be responsible to **IQVIA** for strict compliance by all **Study Staff**, including the **Investigator** and the subinvestigators and **Study Staff**, with the terms of this **Agreement. Institution** shall ensure that any personnel who assist in the conduct of the **Study** are informed of and agree to abide by all terms of this **Agreement** applicable to the activities they perform. Institution will assume all those responsibilities assigned to clinical study sites under all **Applicable Law** including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("**ICH GCP**") guidelines and standards, and all **Applicable Law** relating to the confidentiality, privacy and security of patient information. The **Investigator** shall be responsible and liable for performance of the obligations under this **Agreement** by the **Study Staff** . Any breach committed by the **Study Staff** shall be deemed to be a breach committed by the **Investigator**.

2.2.1 Protocol. **Institution** shall and agrees to ensure that the Investigator and the **Study Staff** conducts the **Study** in accordance with the **Protocol**.

2.2.2 Amendments. The **Protocol** may be modified only by a written amendment, signed by both **Sponsor** and the **Investigator.** The **Parties** acknowledge that **Protocol** amendments are also subject to approval by the responsible Independent Ethics Committee ("**IEC**").

2.2.3 Emergency Amendments. If it is necessary to change the **Protocol** on an emergency basis for the safety of the **Study Subjects**, **Institution** will notify **Sponsor** and/or **IQVIA** and the responsible **IEC** as soon as practicable but, in any event, no later than three working days after the change is implemented. Any emergency change to the **Protocol** must be followed by a written amendment duly executed by **Sponsor** and the **Investigator**.

2.2.4 No Additional Research. **Institution** confirms that no additional research will be conducted on **Study Subjects** during the conduct of the **Study** unless it is approved by **Sponsor** and documented as a companion protocol or an amendment to the original **Protocol.** Such prohibited research activities include analyses of biological samples from **Study Subjects** for any non-therapeutic purpose.

2.2.5 Independent Ethics Committee. Before the **Study** is initiated, **Institution** will ensure that both the **Study** and the informed consent form are approved by an **IEC** that complies with all applicable regulations. **Institution** will further ensure that the **Study** is subject to continuing oversight by the **IEC** throughout its conduct.

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2.2.6 Study Disapproval. If, through no fault of **Institution**, the **Study** is disapproved by the **IEC**, this **Agreement** will immediately terminate with no penalty to the **Institution**, as outlined below.

2.3 Informed Consent Form

Site agrees to use an informed consent form that has been approved by **Sponsor** and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("**IRB**") or Independent Ethics Committee ("IEC") that is responsible for reviewing the **Study**. **Site** shall obtain the prior written informed consent of each **Study Subject**.

2.4 Medical Records and Study Data

2.4.1 Collection, Storage and Destruction: **Site** shall ensure the prompt, complete, and accurate collection, recording and classification of the **Medical Records** and **Study Data**.

Site shall:

(i) maintain and store **Medical Records** and **Study Data** in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with **Applicable Law**, regulations and industry standards, and;

(ii) protect the **Medical Records** and **Study Data** from unauthorized use, access, duplication, and disclosure. If directed by **Sponsor** or **IQVIA**, **Site** will submit **Study Data** using the electronic system provided by **Sponsor** or **IQVIA** or their designated representative and in accordance with **Sponsor's** instructions for electronic data entry. **Site** shall prevent unauthorized access to the **Study Data** by maintaining physical security of the electronic system and ensuring that **Study Staff** maintain the confidentiality of their passwords. **Investigator** agrees to collect all **Study Data** in **Medical Records** prior to entering it into the **CRF**. Site shall ensure the prompt submission of **CRFs**, and;

(iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by **Applicable Law**. Neither **Institution** nor **Investigator** shall destroy or permit the destruction of any **Medical Records** or **Study Data** without prior written notification to the **Sponsor**, and **Institution** shall continue to store **Medical Records** and **Study Data**, at the **Sponsor's** expense, for any period that the **Sponsor** may request in writing after retention is no longer required by any **Applicable Law**.

If the **Investigator** leaves the **Institution**, then responsibility for maintaining **Medical Records** and **Study Data** shall be determined in accordance with applicable regulations but **Institution** will not in any case be relieved of its obligations under this **Agreement** for maintaining the **Medical Records** and **Study Data**.

2.4.2 Ownership. **Institution** shall retain ownership of **Medical Records**. The **Institution** and the **Investigator** hereby assign to **Sponsor** all of their rights, title and interest, including

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intellectual property rights, to all **Confidential Information** (as defined below) and any other **Study Data**.

2.4.3 Access, Use, Monitoring and Inspection. Upon reasonable request, **Site** shall provide original or copies (as the case may be) of all **Study Data** and other **Study** records (including **Study Subject** records and medical charts, **Study Subject** consent documents; drug receipt and disposition logs) to **IQVIA** and **Sponsor** for **Sponsor**'s use. **Site** shall afford **Sponsor** and **IQVIA** and their representatives and designees reasonable access to **Site**'s facilities to examine and inspect the facilities and other activities relating to the **Study** or the **IEC**; and to **Medical Records** and **Study Data** so as to permit **Sponsor** and **IQVIA** and their representatives and designees to monitor and observe the conduct of the **Study**.

Site shall afford regulatory authorities reasonable access to **Site**'s facilities and to **Medical Records** and **Study Data**, and the right to copy **Medical Records** and **Study Data**.

The **Site** agrees to ensure the full cooperation of the **Site**'s researchers, and **IEC** members with any such inspection and with the representatives of **IQVIA** and **Sponsor**, and; **Site** will ensure timely access to applicable records and data to inspections, **IQVIA** and **Sponsor**. **Site** agrees to ensure that the employees, agents and representatives of the **Site** do not harass, or otherwise create a hostile working environment for such representatives. **Site** will promptly resolve any discrepancies that are identified between the **Study Data** and the **Study Subject's Medical Records**.

Site will promptly forward to **Sponsor** or **IQVIA** copies of any inspection findings that **Site** receives from a regulatory agency in relation to the **Study**. Whenever feasible, **Site** will also provide **Sponsor** with an opportunity to prospectively review and comment on any **Site** responses to regulatory agency inspections in regard to the **Study**.

Site will inform **Sponsor** within twenty-four (24) hours of **IQVIA**, and provide **IQVIA** copies of, any effort, inquiries, correspondence or communications to or from any governmental or regulatory authority or other persons to inspect or contact the **Site** or **Study Staff** relating to the **Study**, including, but not limited to, requests for inspection of the **Site**'s facilities, and the **Site** shall permit **IQVIA** and **Sponsor** to attend any such inspections; and will provide **Sponsor** and **IQVIA** the opportunity to participate in any proposed or actual responses by **Site** to such communications. The **Site** will make reasonable efforts to separate, and not disclose, all **Confidential Information** that is not required to be disclosed during such inspections.

2.4.4 License. **Sponsor** hereby grants to **Institution** a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use **Study Data** (i) subject to the obligations set forth in section 5 "**Confidentiality**", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 7 "**Publication Rights**".

2.4.5 Survival. This section 1.11 and 1.12 "**Medical Records** and **Study Data**" shall survive termination or expiration of this **Agreement**.

2.5 Duties of Investigator

INITIALS: IQVIA Institution Investigator

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Site will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the **Study** as subinvestigators or **Study Staff.**

The **Investigator** shall be responsible and liable for performance of the obligations under this **Agreement** by the **Study Staff.** Any breach committed by the **Study Staff** shall be deemed to be a breach committed by the **Investigator.**

Investigator is responsible for the conduct of the **Study at Institution.** In particular, but without limitation, it is the **Investigator**'s duty to review and understand the information in the investigator's brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and **IRBs** or **IECs** are obtained, and to review all **CRFs** to ensure their accuracy and completeness.

Investigator agrees to provide a written declaration revealing **Investigator**'s possible economic or other interests, if any, in connection with the conduct of the **Study** or the **Investigational Product.**

Investigator agrees to provide a written declaration revealing **Investigator's** disclosure obligations, if any, with the **Institution** in connection with the conduct of the **Study** and the **Investigational Product.**

Site agrees to provide prompt advance notice to **Sponsor** and **IQVIA** if **Investigator** will be leaving the **Institution** or is otherwise no longer able to perform the **Study.** The appointment of a new **Investigator** must have the prior approval of **Sponsor** and **IQVIA.**

2.6 Adverse Events

The **Site** shall report adverse events and serious adverse events as directed in the **Protocol** and by **Applicable Law.** The **Site** shall cooperate with **Sponsor** in its efforts to follow-up on any adverse events. The **Site** shall comply with its **IRB/IEC** reporting obligations.

Sponsor will promptly report to the **Site**, the **Site's IRB/IEC,** and **IQVIA,** any finding that could affect the safety of participants or their willingness to continue participation in the **Study,** influence the conduct of the **Study,** or alter the **Site's IRB/IEC** approval to continue the **Study.**

2.7 Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of **Sponsor,** shall supply **Institution** or **Investigator** with sufficient amount of **Investigational Product** as described in the **Protocol.**

The **Site** shall use the **Investigational Product** and any comparator products provided in connection with the **Study,** solely for the purpose of properly completing the **Study** and shall maintain the **Investigational Product** as specified by **Sponsor** and according to **Applicable Law,** including storage in a locked, secured area at all times and will not administer or dispense it to anyone who is not a **Study** subject, or provide access to it to anyone except **Investigator,** subinvestigators, or **Study Staff.**

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Upon completion or termination of the **Study**, the **Site** shall return or destroy, at **Sponsor's** option, the **Investigational Product**, comparator products, and materials and all **Confidential Information** (as defined below) at **Sponsor's** sole expense.

Institution and **Investigator** will use **Investigational Product** or comparator products only as specified in the **Protocol**. Any other use of **Investigational Product** or comparator products constitutes a material breach of this **Agreement**. **Institution** and **Investigator** shall comply with all laws and regulations governing the disposition or destruction of **Investigational Product** and any instructions from **IQVIA** that are not inconsistent with such laws and regulations.

The **Site** shall return any equipment or materials provided by **Sponsor** for use in the **Study** unless **Sponsor** and **Site** have a written agreement for **Site** to acquire the equipment. If there are **Site** facility improvements provided by **IQVIA** or **Sponsor** in relation to the **Study**, then **Site** shall enter a separate written agreement with **IQVIA** or **Sponsor** with respect to such facility improvements.

Investigational Product is and remains the property of **Sponsor**. **Sponsor** grants **Institution** no express or implied intellectual property rights in the **Investigational Product** or in any methods of making or using the **Investigational Product**.

2.8 Biological Samples

If so specified in the **Protocol**, **Investigator** may collect and provide to **Sponsor** or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from **Study Subjects** for testing that is not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("**Biological Samples**").

a) Use. **Site** will not use **Biological Samples** collected under the **Protocol** in any manner or for any purpose other than that described in the **Protocol**.

b) Sample Data. **Sponsor** or its designees will test **Biological Samples** as described in the **Protocol**. Unless otherwise specified in the **Protocol**, **Sponsor** will not provide the results of such tests ("**Sample Data**") to the **Site** or **Study Subject**. **Sample Data** will be treated as **Study Data**; therefore, if **Sponsor** provides **Sample Data** to the **Site**, that data will be subject to the permitted use of **Study Data** as outlined in this **Agreement**.

2.9 Key Enrollment Date

The **Site** understands and agrees that if **Site** has not enrolled at least one (1) **Study Subject** by the **Key Enrollment Date** then **IQVIA** may terminate this **Agreement** in accordance with Section 18 "**Term & Termination**" **Sponsor/IQVIA** has the right to limit enrollment at any time.

3. REPRESENTATIONS AND WARRANTIES

3.1 The **Institution** and the **Investigator** hereby jointly and severally represent and warrant to **IQVIA** the following:

a. The **Investigator** is trained and qualified to conduct clinical trials at the **Study Site**, and the

INITIALS: IQVIA Institution ATTESTED Investigator

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Study Staff working on the **Study** shall be appropriately trained in **ICH GCP** and the **Protocol**;

b. sufficient resource and time is available and shall continue to be available to **Investigator** for dedicated, proper and punctual performance of the **Study** in accordance with the **Protocol** requirements, the terms of this **Agreement**, the **Protocol**, **ICH GCP** and/or other nationally established guidelines and the approval of the **EC**;

c. sufficient resource is allocated and shall continue to be sufficiently allocated and available to Investigator to conduct this **Study**;

d. they possess requisite experience, qualifications, capability and resources including but not limited to, sufficient personnel and equipment to perform the **Study** in a professional and competent manner, and in strict adherence to the **Protocol** and regulatory requirements;

e. the **Investigator** and the **Study Staff** shall perform the **Study** in an efficient and professional manner and shall complete the **Study** within the time period as informed by the **IQVIA** from time to time;

f. they shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective authority(ies) under the applicable regulatory approvals;

g. the **Investigator** and the **Study Staff** shall conduct the **Study** under the review and direct supervision of **IQVIA**, the **EC**, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to co-ordinate, review and safeguard the rights, safety and wellbeing of the **Study Subject**;

h. the representation, warranties set out hereunder may be relied upon in any applications to any of the regulatory authority(ies);

i. they shall not, at all times during the term hereof, neither appoint nor utilize the services nor assign the activities of the **Study** contemplated under the **Protocol** to any subinvestigator(s), who is debarred under any regulatory requirements/laws or statutes from undertaking or performing the **Study** or the obligations hereunder;

j. they shall ensure the safe custody of the **Investigational Product** in accordance with the **Protocol** and shall not use the **Investigational Product** for any purpose other than the purpose of this **Agreement**;

k. they shall notify **IQVIA** of any change in the truth of any of the aforesaid representations;

l. they shall take necessary and appropriate steps to inform its Study Staff of the terms and conditions of this **Agreement** and to ensure that such persons comply with the terms and conditions of this **Agreement**;

m. they shall be accountable to **IQVIA** and **Sponsor** for any and all breach, action, inaction or omission, committed by the **Study Staff**, support staff and personnel provided by it for conducting the **Study**;

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n. in the event the **Study** site is inspected, and the **Study Data** are audited / examined by any regulatory authority(ies) having competent jurisdiction under the regulatory requirements or **Applicable Law**, **Investigator** shall forthwith notify **IQVIA** and/or **Sponsor** of such inspection, inquiry, audit or examination conducted by such regulatory authority(ies);

o. they shall co-ordinate, co-operate with and assist in conducting the **Study** and shall perform such obligations and duties, as may be assigned or imposed upon them, in a timely manner, in accordance with the regulatory requirements and **Applicable Law**;

p. they shall apply for, and obtain, maintain, renew all the applicable approvals during the term of the **Agreement**;

q. they shall perform such other roles, responsibilities and duties as may be required by **IQVIA** from time to time, and;

r. they shall maintain true and complete financial records relating to the **Study** performed under this **Agreement** including costs and expenses incurred in connection with the **Study.**

3.2 Each **Party** hereby represents, warrants and undertakes as follows:

a. it has taken all necessary action on its part required to execute, deliver and perform its obligations under this **Agreement**;

b. this **Agreement** constitutes a legal, valid and binding obligation of the **Parties**, and;

c. neither the execution nor the delivery of this **Agreement** nor its performance would violate any agreement nor constitute a default under any such agreements to which the **Parties** are a party.

3.3 Attendance at Start Up Meeting

If **Sponsor** or **IQVIA** requests **Site's** attendance at a **Study** startup meeting or other meeting necessary to provide information regarding the **Study** or **Investigational Product, Site** will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

4. PAYMENT

In consideration for the proper performance of the **Study** by **Site** in compliance with the terms and conditions of this **Agreement**, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the **Site** completes all its obligations hereunder, and **IQVIA** has received all properly completed **CRFs** and, if **IQVIA** requests, all other **Confidential Information** (as defined below).

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5. CONFIDENTIALITY

5.1 Definition

"**Confidential Information**" means the confidential and proprietary information of **Sponsor** and includes (i) all information disclosed by or on behalf of **Sponsor** to **Institution**, **Investigator** or other **Institution** personnel, including without limitation, the **Investigational Product**, technical information relating to the **Investigational Product**, all **Pre-Existing Intellectual Property** (as defined in Section 6) of **Sponsor**, and the **Protocol**; and (ii) **Study** enrollment information, information pertaining to the status of the **Study**, communications to and from regulatory authorities, information relating to the regulatory status of the **Investigational Product**, and **Study Data** and **Inventions** (as defined in Section 6).

Confidential Information shall not include information that:

(i) can be shown by documentation to have been public knowledge prior to or after disclosure by **Sponsor**, other than through wrongful acts or omissions attributable to **Investigator**, **Institution** or any of its personnel;

(ii) can be shown by documentation to have been in the possession of **Investigator**, **Institution** or any of its personnel prior to disclosure by **Sponsor**, from sources other than **Sponsor** that did not have an obligation of confidentiality to **Sponsor**;

(iii) can be shown by documentation to have been independently developed by **Investigator**, **Institution** or any of its personnel, or ;

(iv) is permitted to be disclosed by written authorization from **Sponsor**.

5.2 Obligations

Site and **Site's** personnel, including **Study Staff** shall not:

(i) use **Confidential Information** for any purpose other than the performance of the **Study**, or;

(ii) disclose **Confidential Information** to any third party, except as permitted by this Section 5 or by Section 7 "**Publication Rights**", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect **Confidential Information**, Site agrees to:

(i) limit dissemination of **Confidential Information** to only those **Study Staff** having a need to know for purposes of performing the **Study**;

(ii) advise all **Study Staff** who receive **Confidential Information** of the confidential nature of such information, and;

(iii) use reasonable measures to protect **Confidential Information** from disclosure.

Nothing herein shall limit the right of **Site** to disclose **Study Data** as permitted by Section 7 "**Publication Rights.**"

5.3 Compelled Disclosure

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In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any **Confidential Information**, the notice recipient shall provide **Sponsor** with prompt notice so that **Sponsor** may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the **Confidential Information** which is legally required to be disclosed and shall request confidential treatment for the **Confidential Information.**

5.4 Return or Destruction

Upon termination of this **Agreement** or upon any earlier written request by **Sponsor** at any time, **Site** shall return to **Sponsor**, or destroy, at **Sponsor**'s option, all **Confidential Information** other than **Study Data.**

5.5 Survival

This Section 5 "**Confidentiality**" shall survive termination or expiration of this **Agreement** for ten (10) years.

6. INTELLECTUAL PROPERTY

6.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the **Effective Date** and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this **Agreement**, and no **Party** or **Sponsor** shall have any claims to or rights in any **Pre-existing Intellectual Property** of another, except as may be otherwise expressly provided in any other written agreement between them.

6.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a **Party** or **Sponsor** or any of such entity's personnel in performance of the **Study. Sponsor** shall own all **Inventions,** that are conceived, first reduced to practice or otherwise discovered or developed by the **Institution,** the **Investigator** or any of their personnel in performance of the **Study.**

6.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all **Inventions** promptly and fully to **Sponsor** in writing, and **Site**, on behalf of itself and its personnel, hereby assigns to **Sponsor** all of its rights, title and interest in and to **Inventions,** including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. **Site** shall cooperate and assist **Sponsor** by executing, and causing its personnel to execute, all documents reasonably necessary for **Sponsor** to secure and maintain **Sponsor**'s ownership rights in **Inventions.**

6.4 License

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Sponsor hereby grants to **Institution** a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use **Inventions**, subject to the obligations set forth in Section 5 "**Confidentiality**," for internal, non-commercial research and for educational purposes.

6.5 Patent Prosecution

Site shall cooperate, at **Sponsor's** request and expense, with **Sponsor's** preparation, filing, prosecution, and maintenance of all patent applications and patents for **Inventions.**

6.6 Survival

This Section 6 "**Intellectual Property**" shall survive termination or expiration of this **Agreement.**

7. PUBLICATION RIGHTS

7.1 Publication and Disclosure

Institution and **Investigator** shall have the right to publish or present the results of **Institution's** and **Investigator's** activities conducted under this **Agreement**, including **Study Data**, only in accordance with the requirements of this section. **Institution** and **Investigator** agree to submit any proposed publication or presentation to **Sponsor** for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, **Sponsor** shall advise **Institution** and/or **Investigator**, as the case may be, in writing of any information contained therein which is **Confidential Information** (other than **Study Data**) or which may impair the availability of patent protection for Inventions. **Sponsor** shall have the right to require **Institution** and/or **Investigator**, as applicable, to remove specifically identified **Confidential Information** (other than **Study Data**) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable **Sponsor** to seek patent protection for **Inventions.**

7.2 Multi-Center Publications

If the **Study** is a multi-center study, **Institution** and **Investigator** agree that they shall not, without the **Sponsor's** prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to **Institution's** and **Investigator's** activities conducted under this **Agreement** until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the **Study** and lock of the database at all research sites or any earlier termination or abandonment of the **Study, Institution** and **Investigator** shall have the right to publish and present the results of **Institution's** and **Investigator's** activities conducted under this **Agreement**, including **Study Data**, solely in accordance with the provisions of Section 7.3 "**Confidentiality of Unpublished Data.**" and 7.1 "**Publication and Disclosure**"

7.3 Confidentiality of Unpublished Data

Institution and **Investigator** acknowledges and agrees that **Study Data** that is not published, presented or otherwise disclosed in accordance with Section 7.1 or Section 7.2 ("**Unpublished Data**") remains within the definition of **Confidential Information**, and **Institution** and **Investigator** shall not, and shall require their personnel not to, disclose **Unpublished Data** to any third party or disclose any **Study Data** to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 7.1 or Section 7.2.

7.4 Media Contacts

Institution and **Investigator** shall not and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the internet, related to the **Study**, the **Investigational Product**; **Inventions**, or **Study Data** without the prior written consent of **Sponsor**. This provision does not prohibit publication or presentation of **Study Data** in accordance with this section.

7.5 Use of Name, Registry and Reporting

No **Party** hereto shall use any other **Party's** name, or **Sponsor's** name, in connection with any advertising, publication or promotion without prior written permission, except that the **Sponsor** and **IQVIA** may use the **Site's** name in **Study** publications and communications, including clinical trial websites and **Study** newsletters. **Sponsor** will register the **Study** with a public clinical trials registry in accordance with **Applicable Law** and will report the results of the **Study** publicly when and to the extent required by **Applicable Law**.

7.6 Survival

This Section 7 **"Publication Rights"** shall survive termination or expiration of this **Agreement.**

8. PERSONAL DATA

8.1 Study Team Member Personal Data

Both prior to and during the course of the **Study**, the **Investigator** and his/her teams may be called upon to provide personal data. This data falls within the scope of the law and regulations relating to the protection of personal data.

For the **Investigator**, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to potential **Dual Capacity** conflict of interest, and payments made to **Payee(s)** under this **Agreement** for the following purposes:

(i) the conduct of clinical trials;
(ii) verification by governmental or regulatory agencies, the **Sponsor**, **IQVIA**, and their agents and affiliates;
(iii) compliance with legal and regulatory requirements;
(iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
(v) storage in databases to facilitate the selection of investigators for future clinical trials; and;
(vi) anti-corruption compliance.

Names of members of **Study Staff** may be processed in **IQVIA's** study contacts database for study-related purposes only.

8.2 Study Subject Personal Data

The **Investigator** shall obtain **Study Subject** written consent for the collection and use of **Study Subject** personal data for **Study** purposes, including the disclosure, transfer and processing of data collected in accordance with the **Protocol**, in compliance with applicable data protection provisions.

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8.3 Data Controller

The **Sponsor** shall be the data controller for such personal data except that, if **IQVIA** deals with any personal data under this **Agreement** in the manner of a data controller, **IQVIA** shall be the data controller of such personal data to the extent of such dealings.

IQVIA may process "**personal data**", as defined in the applicable data protection legislation enacted under the same or equivalent/similar national legislation (collectively "**Data Protection Legislation**"), of the **Investigator** and **Study Staff** for study-related purposes and all such processing will be carried out in accordance with the **Data Protection Legislation.**

8.4 Survival

This Section 8 "**Personal Data**" shall survive termination or expiration of this **Agreement.**

9. STUDY SUBJECT INJURY AND INDEMNIFICATION

9.1 The **Site** shall promptly notify **IQVIA** and **Sponsor** in writing of any claim of illness or injury or death actually or allegedly due to an adverse reaction to the **Investigational Product** and cooperate with **Sponsor** in the handling of the adverse event.

Sponsor shall reimburse **Institution** for the direct, reasonable and necessary medical expenses incurred by **Institution** for the treatment of any adverse event experienced by, illness of or bodily injury to a **Study Subject** that is caused by treatment of the **Study Subject** in accordance with the **Protocol,** except to the extent that such adverse event, illness or personal injury is caused by:

(a) failure by **Institution, Investigator** or **Research Company** or any of their respective personnel to comply with this **Agreement**, the **Protocol**, any written instructions of **Sponsor** concerning the **Study**, or any **Applicable Law**, including **GCPs**, issued by any regulatory authority, or;

(b) negligence, fraud or willful misconduct by **Institution, Investigator** or **Research Company** or any of their respective personnel, or;

(c) failure of the **Study Subject** to follow the reasonable instructions of the Investigator relating to the requirements of the **Study**.

9.2 Notice and Cooperation. **Site** agrees to provide **Sponsor** and/or **IQVIA** with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by **Sponsor** and/or **IQVIA, Site** agrees to authorize **Sponsor** and/or **IQVIA** to carry out the sole management of defense of an indemnified claim.

9.3 Settlement or Compromise. No settlement or compromise of a claim subject to this indemnification provision will be binding on **Sponsor** and/or **IQVIA** without **Sponsor**'s and/or **IQVIA** prior written consent. **Sponsor** and/or **IQVIA** will not unreasonably withhold such consent of a settlement or compromise. Neither **Party** will admit fault on behalf of the other **Party** without the written approval of that **Party.**

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9.4 **Site** (which shall include its employees, agents and representatives) shall have full responsibility for all damages, losses, liabilities, costs or expenses resulting or arising from:

a) failure by the **Institution** and/or the **Investigator**, and the **Study Staff** (which shall include his/her employees, agents and representatives) to comply with the **Applicable Law**, **Protocol**, the terms of this **Agreement**, **ICH GCP** and/or other nationally established guidelines, the approval of the IEC or **Regulatory Authority**, **Protocol** or written instructions from **Sponsor** and/or **IQVIA**;

b) failure by the **Institution** and/or **Investigator** and the **Study Staff** to comply with **Applicable Law**;

c) any negligent act or omission or willful misconduct by the **Institution** and/or **Investigator**, and the **Study Staff** (which shall include his/her employees, agents and representatives), fraud or misrepresentation.

This Section 9 "**Study Subject Injury and Indemnification**" shall survive termination or expiration of this **Agreement**.

10. INSURANCE.

The **Site** will secure and maintain in full force and effect throughout the performance of the **Study** (and following termination of the **Study** to cover any claims arising from the **Study**) insurance coverage for medical professional liability with limits in accordance with the **Applicable Law** for all medical professionals conducting the **Study**.

11. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the **Investigational Product**, including any liability for any claim arising out of a condition caused by or allegedly caused by any **Study** procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this **Agreement** by **IQVIA**.

This Section 11 "**IQVIA Disclaimer**" shall survive termination or expiration of this **Agreement**.

12. CONSEQUENTIAL DAMAGES

Neither **IQVIA** nor **Sponsor** shall be responsible to the **Site** for any lost profits, lost opportunities, or other consequential damages, nor shall **Site** be responsible to **IQVIA** or **Sponsor** for any lost profits, lost opportunities, or other consequential damages.

(a)

This Section 12 "**Consequential Damages**" shall survive termination or expiration of this **Agreement**.

13. DEBARMENT

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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The **Site** represents and warrants that neither **Institution** nor **Investigator**, nor any of **Institution's** or **Investigator's** employees, agents or other persons performing the **Study** at **Institution**, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the **Site** shall notify **IQVIA** immediately if any such investigation, disqualification, debarment, or ban occurs. **Site** also certifies that it is not excluded from any governmental health care program, **Site** further certifies that that it is not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this **Agreement** and for three years after its termination, **Site** will notify **IQVIA** and **Sponsor** promptly in writing [to the extent possible, within two (2) business days] if either of these certifications needs to be amended in light of new information or if **Site** becomes aware of any material issues related to the medical licensure of any associated **Study** researchers (including the **Investigator**).

This Section 13 "**Debarment**" shall survive termination or expiration of this **Agreement**.

14. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon **Sponsor's** or **IQVIA's** request, **Site** agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of **Study Subjects**, it shall promptly return to **IQVIA** a financial and conflict of interest disclosure form that has been completed and signed by such investigator or subinvestigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such **Investigator** and subinvestigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the **Study** and for one (1) year after **Study** completion.

Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, **Sponsor**, **IQVIA**, and their agents, and the **Site** consents to such review.

The **Site** further consents to the transfer of its financial disclosure data to the **Sponsor's** country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the **Site's** own country.

This Section 14 "**Financial Disclosure and Conflict of Interest**" shall survive termination or expiration of this **Agreement**.

15. ANTI-KICKBACK AND ANTI FRAUD

Institution and **Investigator** agree that their judgment with respect to the advice and care of each **Study Subject** will not be affected by the compensation they receive from this **Agreement**, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

If the **Sponsor** or **IQVIA** provides any free products or items for use in the **Study**, **Institution** and **Investigator** agree that they will not bill any **Study Subject**, insurer or governmental agency, or any other third party, for such free products or items.

Institution and **Investigator** agree that they will not bill any **Study Subject**, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from **IQVIA** or **Sponsor**, or which are not part of the ordinary care they would normally provide for the **Study Subject**, and that neither **Institution** nor **Investigator** will pay another physician to refer subjects to the **Study**.

16. ANTI-BRIBERY

Institution and **Investigator** agree that the fees to be paid pursuant to this **Agreement** represent fair compensation for the services to be provided by **Site**. **Institution** and **Investigator** represent and warrant that payments or items of value received pursuant to this **Agreement** or in relation to the **Study** will not influence any decision that **Institution**, **Investigator** or any of their respective owners, directors, employees, agents, consultants, or any payee under this **Agreement** may make, as a **Government Official** or otherwise, in order to assist **Sponsor** or **IQVIA** to secure an improper advantage or obtain or retain business.

Institution and **Investigator** further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this **Agreement**, will, in order to assist **Sponsor** or **IQVIA** to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any items of value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this **Agreement** or at law, **IQVIA** may terminate this **Agreement** if **Site** breaches any of the representations or warranties contained in this **Section** or if **IQVIA** or **Sponsor** learns that improper payments are being or have been made to or by **Institution** or **Investigator** or any individual or entity acting on its or their behalf.

17. INDEPENDENT CONTRACTORS

The **Investigator** and **Institution** and **Research Company** and **Study Staff** are acting as independent contractors of **IQVIA** and **Sponsor** and shall not be considered the employees or agents of **IQVIA** or **Sponsor**.

Neither **IQVIA** nor **Sponsor** shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the **Investigator** or **Institution** or **Research Company** or their staff.

It is hereby agreed and acknowledged by the **Parties** and **Sponsor** that **IQVIA** has no relationship whatsoever with the **Research Company** and that the **Research Company** is acting as an independent contractor of the **Institution**.

ATTESTED
Institution

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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18. TERM & TERMINATION

18.1 Term

This **Agreement** will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever date is later, (the "**Effective Date**") and shall continue until completion or until terminated in accordance with this Section 18 "**Term & Termination**". **IQVIA** shall attach a copy of the approval from the Drugs Controller General India approving the **Study** to this **Agreement** as Attachment B, and the **Parties** agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the **Parties** sign this **Agreement, IQVIA** shall keep the original signed **Agreements** until receipt of such approval, and upon receipt of such approval, **IQVIA** shall attach a copy of the approval to each original **Agreement** as Attachment B and forward an original **Agreement** to each other **Party** thereafter, while retaining one original **Agreement** in its files. If such approval was received prior to the signatures of the **Parties, IQVIA** shall attach a copy of the approval hereto as Attachment B, and upon signature of all **Parties**, each **Party** shall receive an original of the **Agreement,** which shall include such approval as Attachment B.

18.2 Termination

IQVIA may terminate this **Agreement** for any reason effective immediately upon written notice. The **Site** may terminate upon written notice if circumstances beyond the **Site's** reasonable control prevent completion of the **Study**, or if it reasonably determines that it is unsafe to continue the **Study**. Upon receipt of notice of termination, the **Site** shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and **IQVIA** shall make a final payment for visits or milestones properly performed pursuant to this **Agreement** in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by **Sponsor** of all **CRF** pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this **Agreement** appears to have occurred and termination may be required, then, except to the extent that **Study Subject** safety may be jeopardized, **IQVIA** may suspend performance of all or part of this **Agreement**, including, but not limited to, **Study Subject** enrollment.

19. Inspections and Audits.

19.1 Access. Upon reasonable request, **Sponsor**, authorized representatives of **Sponsor**, and/or authorized representatives of the applicable regulatory authority, may during regular business hours examine and copy: all **CRFs** and other trial records (including **Study Subject** records and medical charts; **Study Subject** consent documents; drug receipt and disposition logs); examine and inspect the facilities and other activities relating to the **Study** or the IEC; and observe the conduct of the **Study**.

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

19.2 Notice. **Site** will inform **Sponsor** within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Site or research staff with regard to the **Study**; will provide **Sponsor** or **IQVIA** with a copy of any communications sent by such persons; and will provide **Sponsor** or **IQVIA** the opportunity to participate in any proposed or actual responses by **Site** to such communications.

19.3 Cooperation. **Site** will ensure the full cooperation of the **Site** researchers, and **IEC** members with any such inspection and will ensure timely access to applicable records and data. **Site** will promptly resolve any discrepancies that are identified between the **Study Data** and the **Study Subject's Medical Records**. **Site** will promptly forward to **Sponsor** or **IQVIA** copies of any inspection findings that **Site** receives from a regulatory agency in relation to the Study. Whenever feasible, **Site** will also provide **Sponsor** with an opportunity to prospectively review and comment on any **Site** responses to regulatory agency inspections in regard to the Study.

20. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered
(a) in person,
(b) by certified mail, postage prepaid, return receipt requested,
(c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
(d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	Name: Dr. Dhananjay Bakhle Address: Lupin Limited (Research Park) 46A/47A, Nande, Tal-Mulshi, Pune-412 115 Maharashtra, India Tel: +91-20-66749454
To IQVIA	IQVIA RDS (India) Private Limited (formerly Quintiles Research (India) Private Limited), III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India Tel: +91 8071317778
To Institution	Name: Dr. M. V Jali Address: KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belagavi- 590010, Karnataka, India Tel: 0831 - 2473777
To Investigator	Name: Dr. Archana Uppin Address: KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belagavi- 590010, Karnataka, India

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

	Tel: +91 8944175418
To Research Company	Name: Ms. Nidhi Singh Address: CMS Clinical Research Pvt. Ltd., Inox Towers, Plot No.- 17, Sector 16, A Film City, Noida- 201301, Uttar Pradesh, India Tel: +91 7906261455

21. **FORCE MAJEURE**

The performance by either **Party** of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the **Party** bound by such obligation, provided, however, that the **Party** affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

22. **MISCELLANEOUS**

22.1 Entire Agreement

This **Agreement**, including its attachment(s), constitutes the sole and complete agreement between the **Parties** and replaces all other written and oral agreements relating to the **Study.**

22.2 No Waiver/Enforceability

Failure to enforce any term of this **Agreement** shall not constitute a waiver of such term.

If any part of this **Agreement** is found to be unenforceable, the rest of this **Agreement** will remain in effect.

22.3 Assignment of the Agreement

This **Agreement** shall be binding upon the **Parties** and their successors and assigns.

The **Site** shall not assign or transfer any rights or obligations under this **Agreement** without the written consent of **IQVIA** and **Sponsor.**

Upon Sponsor's request, **IQVIA** may assign this **Agreement** to **Sponsor** or to a third party, and **IQVIA** shall not be responsible for any obligations or liabilities under this **Agreement** that arise after the date of the assignment, and the **Site** hereby consents to such an assignment. **Site** will be given prompt notice of such assignment by the assignee.

22.4 Third Party Beneficiary

The **Parties** agree that **Sponsor** shall have the right to enforce any of the provisions of this **Agreement** as a third party beneficiary.

Each **Party** to this **Agreement** acknowledges that except for the **Sponsor**, there are no third party beneficiaries with any rights to enforce any of the provisions of this **Agreement.**

ATTESTED
Prof. Dr. V.A. KOTHIVALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

22.5 Applicable Law
This **Agreement** shall be interpreted under the laws of the state or province and country in which **Site** conducts the **Study.**

22.6 Conflict with Attachments. To the extent that terms or provisions of this **Agreement** conflict with the terms and provisions of the **Protocol**, the terms and provisions of this **Agreement** will control as to legal and business matters, and the terms and provisions of the **Protocol** will control as to technical research and scientific matters unless expressly agreed in a writing between the parties.

22.7 Survival:
The terms of this **Agreement** that contain obligations or rights that extend beyond the completion of the **Study** shall survive termination or completion of this **Agreement**, even if not expressly stated herein.

ATTESTED
Investigator

Prof. L. [illegible]
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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ACKNOWLEDGED AND AGREED BY IQVIA RDS (India) Private Limited
(formerly Quintiles Research (India) Private Limited)

By: Tanuka Ganguly

Title: Director-Site & Patient Networks

Signature: Tanuka Ganguly

Date: 30/Nov/2018

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Archana Uppin

Title: Principal Investigator

Signature: 19/12/18

Date:

Dr. ARCHANA M. UPPIN
Consultant Physician and Rheumatologist
KMC Reg. No. 84197
KLES Dr. Prabhakar Kore Hospital &
MRC, Belagavi

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER:

By: Dr. M. V. Jali

Title : Medical Director

Signature: 13/12/18

Date:

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

Research Company agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 5); Intellectual Property (Section 6); Publication Rights (Section 7); Debarment (Section 13); Anti Kickback and Anti Fraud (Section 15); and Anti-Bribery (Section 16)

ACKNOWLEDGED AND AGREED BY CMS CLINICAL RESEARCH PVT. LTD.,

By: Ms. Nidhi Singh

Title : Head- Clinical Operations

Signature: 15-12-18

Date:

CMS CLINICAL RESEARCH PVT. LTD. Date

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

WILL NEED TO BE REVIEWED BY THE IPA GROUP

A. PAYEE DETAILS

The **Parties** agree that the payee designated below is the proper payee for this **Agreement**, and that payments under this **Agreement** will be made only to the following payee ("**Payee**"):

Payee Name	CMS Clinical Research Private Limited
Payee Address	Inox Towers, Plot No.- 17, Sector 16, A Film City, Noida- 201301, Uttar Pradesh, India
Bank Name	HDFC Bank
Bank Account number	50200007478582
IFSC Code	HDFC0000368
GST registration number	09AAFCC8457M1ZZ
Permanent Account Number	AAFCC8457M

In case of changes in the Payee's bank details, Site is obliged to inform IQVIA in writing. The Parties agree that in case of changes in bank details which do not involve a change of Payee/Bank Account Name or change of country location of bank account, no further amendments are required.

The **Parties** acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this **Agreement.**

If the **Investigator** is not the **Payee**, then the **Payee's** obligation to reimburse the **Investigator**, if any, is determined by a separate agreement between **Investigator** and **Payee**, which may involve different payment amounts and different payment intervals than the payments made by **IQVIA** to the **Payee**.

Investigator acknowledges that if **Investigator** is not the **Payee**, **IQVIA** will not pay **Investigator** even if the **Payee** fails to reimburse **Investigator.**

B. PAYMENT TERM

IQVIA will pay the **Payee** monthly or **Quarterly**, on a completed visit per **Study Subject** basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any screening failure that may be payable under the terms of this **Agreement**, will be made based upon prior month/3 months' [*to adjust depending the payment frequency*] enrollment data confirmed by **Study Subject's** CRF received from the **Site** supporting **Study Subject** visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual Study Subject visits, and will be paid by **IQVIA** to the **Payee** upon final acceptance by **Sponsor** of all **CRFs** pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by **IQVIA** and/or **Sponsor**, the return of all unused supplies to **IQVIA**, and upon satisfaction of all other applicable conditions set forth in the **Agreement.**

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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Any expense or cost incurred by **Site** in performing this **Agreement** that is not specifically designated as reimbursable by **IQVIA** or **Sponsor** under the **Agreement** (including **this Budget and Payment Schedule**) is **Site's** sole responsibility.

Site shall be responsible to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this **Agreement** including, without limitation, those that relate to the **Investigator**, the **Institution** and its employees and/or collaborators.

Site represents that the services it provides under this **Agreement** are taxable services under the laws governing Goods and Services Tax ("**GST**") in India, and that it is required to charge **GST** for the services rendered to **IQVIA** at the prevailing rate. **Site** represents that it is entitled to require such payment of the **GST** under the laws of India. **Site** undertakes to provide **IQVIA** with an invoice, to be sent to **IQVIA** at the address mentioned in Section F of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this **Agreement** are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

Major, disqualifying Protocol violations are not payable under this Agreement

C. **PAYMENT DISPUTE**
Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the **Study**.

D. **MINIMUM ENROLMENT GOAL**
Site acknowledges that **Site's** minimum enrollment goal is **6 Study Subjects** and that **Site** will use best efforts to reach the enrollment goal within a reasonable time after commencement of the **Study** at **Site**. If **Site** fails to adhere to this principle **IQVIA** may reconsider **Site's** suitability to continue participation in the **Study**.

E. **DISCONTINUED OR EARLY TERMINATION**
Reimbursement for discontinued or early termination of **Study Subjects** will be prorated based on the number of confirmed completed visits.

F. **INVOICES**
Original Invoices pertaining to this **Study** for the following items must be submitted to **IQVIA** for reimbursement at the following address:

IQVIA RDS (India) Private Limited
(formerly Quintiles Research (India) Private Limited)
Attn: Accounts Payable
Address: III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India
Phone: +91 8071317779

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator name and site number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

G. Screening Failure

Reimbursement for screen failures will be at the amount indicated on the screening visit of the attached budget, not to exceed 4 screen failure(s) paid per 1 **Study Subject**(s) randomized.

To be eligible for reimbursement of a screening visit, completed screening **CRF** pages must be submitted to **IQVIA** along with any additional information, which may be requested by **IQVIA** to appropriately document the **Study Subject** screening procedures.

H. Unscheduled visits

Payment for unscheduled visits will be reimbursed in the amount of **Three Thousand Five Hundred Eighty (3,580 INR)** [which includes overhead]. To be eligible for reimbursement for unscheduled visits, completed **CRF** pages must be submitted to **IQVIA** along with any additional information which may be requested by **IQVIA** to appropriately document the unscheduled visit.

I. EC/IRB/IEC fees

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the **EC/IRB/IEC** and are not included in the attached Budget. Payment will be made directly to the **EC/IRB/IEC.** Any subsequent re-submissions or renewals, upon approval by **IQVIA** and **Sponsor,** will be reimbursed upon receipt of appropriate documentation.

J. Budget table

Visit	PI Grant	CRC Grant	Institutional Overhead 25%	Administrative Charges	Patient Travel Reimbursement	Total Cost Per Patient (INR)**
Screening/SCR	6,800	3,000	2,450	500	500	13, 250
Day 1/WK1	6,325	2,000	2,081	500	500	11, 406
Day 22/WK4	6,250	2,000	2,062	500	500	11, 312
Day 43/WK7	6,250	2,000	2,062	500	500	11, 312
Day 64/WK10	6,250	2,000	2,062	500	500	11, 312
Day 78/WK12	6,325	2,000	2,081	500	500	11, 406
Day 84/EOS	6,800	3,000	2,450	500	500	13, 250
Total Cost Per Patient (INR)	**45,000**	**16,000**	**15,248**	**3500**	**3500**	**83, 248**

*The PI grants include ECG and X-ray Charges.
** Total cost include laboratory cost and procedures for each scheduled visit.

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

All payments for this **Study** in accordance with the attached budget will be paid by **IQVIA** by wire transfer.

These amounts include all taxes except applicable GST tax.

ATTESTED
Institution
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ADDENDUM TO CLINICAL TRIAL SITE AGREEMENT FOR 0804-16 STUDY
("Addendum")

1 PREAMBLE AND INTENTION

The Parties are,

1.1 **Lambda Therapeutic Research Ltd.**, a company incorporated in accordance with the laws of India with its registered office at Lambda house, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad – 382481, Gujarat, India (herein referred to as "Lambda") (which expression shall unless repugnant to the context or meaning thereof be deemed to include its affiliates, employees, subsidiaries, nominees, successors - in - interest and assigns)

AND:

Principal Investigator, **Dr. Shiva Kumar Patil**, KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND:

KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India
(Hereinafter referred to as the "Institute")

AND:

Site Management Organization, KV Clinical Research Services Office no. 615, 6th Floor Golden Trade Centre New Rajendra Nagar, Raipur – 492001, Chhattisgarh
(Hereinafter referred to as the "SMO")

CRO, Site, SMO and Principal Investigator are hereinafter individually referred to as a "Party" and collectively as the "Parties".

WHEREAS:

1.2 Parties have entered into a Clinical Trial Site Agreement dated April 05, 2018 (herein referred to as "Agreement"), pursuant to which CRO, acting as an independent contractor on behalf of SPONSOR desires to coordinate a clinical research study, Site and Principal Investigator agreed to facilitate and carry out the Study as detailed in Agreement.

1.3 The Parties wish to amend and supplement certain of the terms of the Agreement as recorded herein ("Addendum").

LAMBDA Research Accelerated
Prof. Dr. V. A. KATHHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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1.4 This Addendum forms part of and is to be read with the Agreement as from **June 21, 2018** ("Effective Date").

2 AMENDMENTS

As requested by Investigator to increase the "Investigator Grant" amount of **INR 49,920** (per patient) as per **attachment – A (Revised Budget);**

In addition to this LAMBDA, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the SMO, Institution & PI. Details of Payee are:

Payee Details:

Payee Name	:	"KV Clinical Research Services Payable" at Raipur
Payee Address	:	AAPFK7058P
PAN / TAN Number	:	MIG II /253 Sector -1, Pt. Deendayal Upadhyay Nagar, Raipur – 492001, Chhattisgarh
GST Number	:	22 AAPFK7058P1ZM

ATTESTED

LAMBDA Research Accelerated

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

A. Revised Budget:

FINANCE SUMMARY BOX	
Invoice Currency	INR
Study Base	Visit-based
Effective Date	The revised budget will be applicable from 21 June 2018

Sr. No.	Payment Head	Screening/Visit 01	Visit 02	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9/ EoT + EoS	Total
		Up to 14 days prior to dosing	Day 0	Day 7	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84 + 7 days	
1	Investigator Grant	3200	2250	2250	2250	2250	2250	2250	2250	3000	21950
2	Study Coordinator Grant	1500	1200	1200	1200	1200	1200	1200	1200	1500	11400
3	ECG (12 Lead)	500	[redacted]							500	1000
4	X-Ray	500									500
5	Institutional Overhead (20%)	1140	690	690	690	690	690	690	690	1000	6970
6	Target Lesion Photograph Print	[redacted]	450	450	450	450	450	450	450	450	3600
	Total										
7	Patient Compensation (actuals)	500	500	500	500	500	500	500	500	500	4500
	Total Grand/patient										**49920**
8	**Local Laboratory Investigation**										
8a	Haematology	420	[redacted]							420	**840**
8b	Blood/Serum Biochemistry	1430								1430	**2860**
8c	Immunology	1200								1200	**2400**
8d	Urinalysis	150								150	**300**
8e	Pregnancy Tests	150	**UPT kit will be provided by Lambda**							150	**300**
	TOTAL OF SECTION 8										**6700**
	Local lab Investigations: Haematology, Biochemistry, Immunology, Serum pregnancy test and Urine analysis investigations will be done as per protocol requirement on Visit 1 and Visit 9 only.										
	Note:										

1. The above referenced per patient grant will remain same throughout the study. Additionally investigator/site will get a bonus amount of INR 20,000 after enrollment of every 10th patient in the study.

2. Phlebotomist activities will be completed by site team only. No additional cost will be paid for the same.

3. Patient compensation will be provided based on actual bills only (provided is upper limit)

3 GENERAL

3.1 As of the Effective Date, this Addendum 1 shall be read together with and shall be deemed to be incorporated in the Agreement and shall be governed by the terms, conditions and definitions set forth in the Agreement, as if such terms were fully set forth herein.

3.2 Except as expressly amended hereby, the terms and conditions of the Agreement shall continue in full force and effect and are hereby confirmed and ratified.

SIGNATORIES

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate as of the date and year first above written.

Lambda Therapeutic Research Ltd.

By: Ravesh
Printed Name: Too. Ravesh Patel
Title: AVP - CTM
Date: 23 Jun 2018

PRINCIPAL INVESTIGATOR

By:
Printed Name: Dr. Shivakumar Patil
Title: Consultant Dermatologist
Date: 29 Jun 2018

SMO

By:
Printed Name: Kirti Kumar Patel
Title: Founders COO
Date: 21 July 18

INSTITUTION

By:
Printed Name: Dr. M. V. Jali
Title: MD & CE, KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010.
Date: 16 Jul 2018

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LAMBDA Research Accelerated
Prof. Dr. V. S. KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

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CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and between:

- **KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre** , having a place of business at Nehru Nagar, Belagavi - 590010, Karnataka, India (the "**Institution**"), and
- **Dr. Kothiwale Veerappa Annasaheb** , having a place of business at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India (the "**Investigator**"), and
- **GDD Experts India Pvt. Ltd.**' having a place of business at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur-440001, Maharashtra, India (the "**Research Company**")and
- **Quintiles Research (India) Private Limited**, having a place of business at B-101-106, Shapath IV, Opposite Karnavati Club, Sarkhej Gandhinagar Road, Ahmedabad - 380 051, Gujarat, India ("**Quintiles**"),

Each a "**Party**" and together the "**Parties**".

Protocol Number:	1002-043
Protocol Title:	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFECTS OF BEMPEDOIC ACID (ETC-1002) ON THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN PATIENTS WITH, OR AT HIGH RISK FOR, CARDIOVASCULAR DISEASE WHO ARE STATIN INTOLERANT
Protocol Date:	24 June 2016
Sponsor:	Esperion Therapeutics, Inc.
Country where Site is Conducting Study	India
Investigator:	Dr. Kothiwale Veerappa Annasaheb
Key Enrollment Date:	100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrollment Date" below)
IRB/IEC	Ethics Committee of KLE University JNMC Campus, Nehru Nagar, Belgaum - 590010, Karnataka , India EC chairperson/chairman name : Dr. Subarna Roy Contact No. of the EC chairperson/chairman: +91 9449033133

The following additional definitions shall apply to this Agreement:

Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Case Report Form or **CRF**: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or **GCPs**: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs, and other diagnostic images.

MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as

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enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

Dual Capacity: the capacity of holding a Government Official position and being a party to this Agreement.

RECITALS:

WHEREAS, Quintiles is providing clinical research organisation services to Sponsor under a separate contract between Quintiles and Sponsor. Quintiles' services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution and Investigator (hereinafter jointly the "**Site**") are willing to conduct the Study and Quintiles requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs and MCI Regulations and state and local tax and finance regulations. Site and Study Staff acknowledge that Quintiles and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("**IRB**") or Independent Ethics Committee ("**IEC**") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.

1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall

(i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and

(ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or Quintiles, Site will submit Study Data using the electronic system provided by Sponsor or Quintiles or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all

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Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and

(iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by applicable laws and regulations. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Sponsor, and Institution shall continue to store Medical Records and Study Data, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any applicable law or regulation.

If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to Quintiles and Sponsor for Sponsor's use. Site shall afford Sponsor and Quintiles and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and Quintiles and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of Quintiles and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify Quintiles of, and provide Quintiles copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit Quintiles and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

1.3.4. License. Sponsor hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data solely (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the

information in the Investigator's Brochure, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.
Site agrees to provide prompt advance notice to Sponsor and Quintiles if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and Quintiles.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and Quintiles, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by Sponsor and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from Quintiles that are not inconsistent with such laws and regulations.

The Site shall return any equipment or materials provided by Sponsor for use in the Study unless Sponsor and Site have a written agreement for Site to acquire the equipment. Equipment provided to Site for the Study, if any, is listed on Attachment C hereto. If there are Site facility improvements provided by Quintiles or Sponsor in relation to the Study, then Site

shall enter a separate written agreement with Quintiles or Sponsor with respect to such facility improvements.

1.7. Enrollment of Patients

The Effective Date of this Agreement is as listed in Section 15. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any payment until the validity date of this Agreement is reached.

1.8. Key Enrollment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then Quintiles may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/Quintiles has the right to limit enrollment at any time.

1.9. Attendance at Start Up Meeting

If Sponsor or Quintiles requests Site's attendance at a Study startup meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

2. PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and Quintiles has received all properly completed CRFs and, if Quintiles requests, all other Confidential Information (as defined below). Institution and Investigator acknowledge and confirm that if Investigator is a named payee hereunder, such payment arrangement is in accordance with the modalities laid down by the Institution for receipt of funding for the Study and is not in violation of the MCI Regulations.

3. CONFIDENTIALITY

3.1 Definition

"Confidential Information" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

(i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;

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(ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;
(iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or
(iv) is permitted to be disclosed by written authorization from Sponsor.

3.2 Obligations

Site and Site's personnel, including Study Staff shall not

(i) use Confidential Information for any purpose other than the performance of the Study or
(ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

(i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study, provided that such persons are subject to a written agreement or otherwise bound by a duty of confidentiality, respecting the Confidential Information in the manner set forth in this Agreement;
(ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and
(iii) use reasonable measures to protect Confidential Information from disclosure.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Publication Rights."

3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

3.5 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by

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this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions.

4.4 License

Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality", solely for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section 5. Institution and Investigator agree to submit any proposed publication or presentation to Sponsor for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, Sponsor shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the

availability of patent protection for Inventions. Sponsor shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Sponsor to seek patent protection for Inventions.

5.2 Multi-Center Publications

If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the Sponsor's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section 5.3 "Confidentiality of Unpublished Data."

5.3 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 5.1 or Section 5.2 ("Unpublished Data") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 5.1 or Section 5.2.

5.4 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

5.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and Quintiles may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.6 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

6.1 Study Team Member Personal Data

Both prior to and during the course of the Study, the Investigator and his/her teams may be called upon to provide personal data. This data falls within the scope of the law and regulations relating to the protection of personal data.

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For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to potential Dual Capacity conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

(i) the conduct of clinical trials;
(ii) verification by governmental or regulatory agencies, the Sponsor, Quintiles, and their agents and affiliates;
(iii) compliance with legal and regulatory requirements;
(iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
(v) storage in databases to facilitate the selection of investigators for future clinical trials; and
(vi) anti-corruption compliance.

Names of members of Study Staff may be processed in Quintiles' study contacts database for study-related purposes only.

6.2 Study Subject Personal Data

The Investigator shall obtain Study Subject written consent for the collection and use of Study Subject personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable data protection provisions.

6.3 Data Controller

The Sponsor shall be the data controller for such personal data except that, if Quintiles deals with any personal data under this Agreement in the manner of a data controller, Quintiles shall be the data controller of such personal data to the extent of such dealings.

Quintiles may process "**personal data**", as defined in the applicable data protection legislation enacted under the same or equivalent/similar national legislation (collectively "Data Protection Legislation"), of the Investigator and Study Staff for study-related purposes and all such processing will be carried out in accordance with the Data Protection Legislation.

6.4 Survival

This Section 6 "Personal Data" shall survive termination or expiration of this Agreement.

7. STUDY SUBJECT INJURY

The Site shall promptly notify Quintiles and Sponsor in writing of any claim of illness or injury or death actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:

(a) failure by Institution, Investigator [*or Research Company*] or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or

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(b) negligence or willful misconduct by Institution, Investigator [*or Research Company*] or any of their respective personnel, or
(c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "Study Subject Injury" shall survive termination or expiration of this Agreement.

8. QUINTILES DISCLAIMER

Quintiles expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by Quintiles.

This Section 8 "Quintiles Disclaimer" shall survive termination or expiration of this Agreement.

9. CONSEQUENTIAL DAMAGES

Neither Quintiles nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to Quintiles or Sponsor for any lost profits, lost opportunities, or other consequential damages.

Notwithstanding anything contained herein the Institution shall be liable:

(a) for any act or omission of the Investigator with respect to the payment received by the Investigator in the capacity of the Payee; and
(b) any consequential damages including but not limited to loss of profits and opportunities arising out of the act or omission of the Investigator as set out above.

This Section 9 "Consequential Damages" shall survive termination or expiration of this Agreement.

10. DEBARMENT

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify Quintiles immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or Quintiles' request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to Quintiles a financial and conflict of interest disclosure form that has been

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completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators, or sub-investigators or their spouses or dependent children.

Quintiles may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.
Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Quintiles, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 11 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

12. ANTI-KICKBACK AND ANTI FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or Quintiles provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from Quintiles or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

13. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or Quintiles to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or Quintiles to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or

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entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, Quintiles may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if Quintiles or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

14. INDEPENDENT CONTRACTORS

The Investigator and Institution *and Research Company* and Study Staff are acting as independent contractors of Quintiles and Sponsor and shall not be considered the employees or agents of Quintiles or Sponsor.

Neither Quintiles nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution *or Research Company*or their staff.

It is hereby agreed and acknowledged by the Parties and Sponsor that Quintiles has no relationship whatsoever with the Research Company and that the Research Company is acting as an independent contractor of the Institution.

15. TERM & TERMINATION

15.1 Term

This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever date is later, (the "**Effective Date**") and shall continue until completion or until terminated in accordance with this Section 15 "Term & Termination". Quintiles shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and the Parties agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the Parties sign this Agreement, Quintiles shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, Quintiles shall attach a copy of the approval to each original Agreement as Attachment B and forward an original Agreement to each other Party thereafter, while retaining one original Agreement in its files. If such approval was received prior to the signatures of the Parties, Quintiles shall attach a copy of the approval hereto as Attachment B, and upon signature of all Parties, each Party shall receive an original of the Agreement, which shall include such approval as Attachment B.

15.2 Termination

Quintiles may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if circumstances beyond the Site's reasonable control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all

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reasonable efforts to minimize further costs, and Quintiles shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, Quintiles may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

16. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered

(a) in person,
(b) by certified mail, postage prepaid, return receipt requested,
(c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
(d) by a commercial overnight courier that guarantees next day delivery and provides a receipt,
and such notices shall be addressed as follows:

To Sponsor:	Attention: Narendra Lalwani Name: Esperion Therapeutics, Inc. Address: 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108, USA Tel: 1-734-887-3903 e-mail: nlalwani@esperion.com
To Quintiles	Name: Quintiles Research (India) Private Limited Address: Quintiles Research (India) Private Limited, Natraj By Rustomjee, 6th Floor,194, M. V. Road Junction, Western Express Highway Metro Station, Andheri (East), Mumbai-400069, India Tel: +91 22 66774242
To Institution	Name: Dr. M. V. Jali Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: 0831-2473777
To Investigator	Name: Dr. Kothiwale Veerappa Annasaheb

	Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: +91-9448119899
To Research Company	Name: Dr. Vinod Gyanchandani Address: GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India Tel: +91 9923000560

17. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

18. MISCELLANEOUS

18.1 Entire Agreement

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

18.2 No Waiver/Enforceability

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

18.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of Quintiles and Sponsor.

Upon Sponsor's request, Quintiles may assign this Agreement to Sponsor or to a third party, and Quintiles shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

18.6 Survival:

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

THIS SECTION IS INTENTIONALLY LEFT BLANK

ACKNOWLEDGED AND AGREED BY QUINTILES RESEARCH (INDIA) PRIVATE LIMITED:

By: Subashri Shivkumar

Title: Sr. Director and Head Clinical Development Services

Signature: Subashri Shivkumar

Date: 25/Sept/2017

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

By: Dr. Kothiwale Veerappa Annasaheb

Title: Principal Investigator

Signature: _____

Date: 23 oct 2017

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE:

By: Dr. M. V. Jali

Title: Medical Director

Signature: _____

Date: 23 oct 2017

Research Company agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Publication Rights (Section 5); Debarment (Section 10); Anti Kickback and Anti Fraud (Section 12); and Anti-Bribery (Section 13)

ACKNOWLEDGED AND AGREED BY GDD Experts India Pvt. Ltd.:

By: Dr. Vinod Gyanchandani

Title : Head- Clinical Operations

Signature: _____

Date: 26/oct/2017

Prof Dr V.A.KOTHIWALE
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ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("**Payee**"):

Payee Name	GDD Experts India Pvt. Ltd.
Payee Address	GDD Experts India Pvt. Ltd., Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
Bank Name	Axis Bank Ltd
Bank Account Number	910020034162231
IFSC code	UTIB0000048
GST Registration Number	27AADCG0363Q1ZA
Permanent Account Number (PAN) of Payee	AADCG0363Q
PAYMENT METHOD	Electronic Fund Transfer
Pan #	AADCG0363Q

In case of changes in the Payee's bank details, Site is obliged to inform Quintiles in writing. The Parties agree that in case of changes in bank details which do not involve a change of Payee/Bank Account Name or change of country location of bank account, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.
If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by Quintiles to the Payee.
Investigator acknowledges that if Investigator is not the Payee, Quintiles will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT TERM

Quintiles will pay the Payee **Quarterly**, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including one Screening Failure per randomized subject that may be payable under the terms of this Agreement, will be made based upon prior 3 months enrollment data confirmed by subject CRFs received from the Site supporting subject visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by Quintiles to the Payee upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Quintiles and/or Sponsor, the return of all unused supplies to Quintiles, and upon satisfaction of all other applicable conditions set forth in the Agreement.

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by Quintiles or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Site shall be responsible to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to the Investigator, the Institution and its employees and/or collaborators.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Goods and Services Tax ("GST") in India, and that it is required to charge GST for the services rendered to Quintiles at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide Quintiles with an invoice, to be sent to Quintiles at the address mentioned in Section F of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

Major, disqualifying Protocol violations are not payable under this Agreement

C. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

D. MINIMUM ENROLMENT GOAL

Site acknowledges that Site's minimum enrollment goal is _25____ subjects and that Site will use best efforts to reach the enrollment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle Quintiles may reconsider Site's suitability to continue participation in the Study.

E. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects who continue in the study with visits will be paid as a normal subject, subjects who discontinue treatment and visits will be prorated based on the number of confirmed completed visits.

F. SCREENING FAILURE

Reimbursement for screen failures at Screening Visit 1 will be at a rate of **Sixteen Thousand Four Hundred and Forty Three Rupees (INR 16,443)**. Reimbursement for screen failures at Screening Visit 2 will be the Screening Visit 1 Screen Fail rate plus an additional **Fifteen Thousand and Ninety Rupees (INR15,090).** Reimbursement for Screen failures at Treatment 1 Visit will be at a rate of Five Thousand Seven Hundred and Fourteen Rupees (INR 5,714) plus Screening Failure Visit1 plus Screeen Failure Visit2. Reimbursement of Screen Failures shall not to exceed one (1) screen failures paid per one (1) subject randomized.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to Quintiles along with any additional information, which may be requested by Quintiles to appropriately document the subject screening procedures.

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G. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of is Six Thousand Six Hundred and Fifty Rupees(INR 6,650). [which includes overhead]. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to Quintiles along with any additional information which may be requested by Quintiles to appropriately document the unscheduled visit.

H. ADDITIONAL UNSCHEDULED VISIT PROCEDURES

Additional Unscheduled Visit procedures costs that are not captured in the attached budget will be reimbursed on a pass-through basis upon receipt of invoice. To be eligible for reimbursement subject number, procedure, and date of service must be included on the invoice along with any additional information which may be requested by Quintiles to appropriately document the unscheduled visit procedure.

I. CONDITIONAL PROCEDURES

The following conditional procedures costs will be reimbursed on a pass-through basis upon receipt of invoice at amount indicated in the below table [which includes overhead]. Subject number and visit/dates must be included on the invoice for payment to be issued.

PROCEDURE	PROCEDURE AMOUNT (INR)
Blood draw, venipuncture, phlebotomy specimen collection with lab handling and shipping; simple (serology, serum Pregnancy, TSH, clinical safety lab, basic fasting lipids, HBA 1c, HsCRP)	725
12-lead ECG: Includes tracing, interpretation and report	665
Screen Failure S1	16,443
Screen Failure S2	15,090
Serious Adverse events (SAE)	1451

J. INVOICES

Original Invoices pertaining to this Study for the following items must be submitted to Quintiles for reimbursement at the following address:

Quintiles Research India Private Ltd., Bangalore
Attention: Finance PSC – Accounts Payable (Investigator Payments)
III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator name and site number and Institution GST registration number.. **After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.**

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- **EC/IRB/IEC FEES**

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made directly to the EC/IRB/IEC. Any subsequent re-submissions or renewals, upon approval by Quintiles and Sponsor, will be reimbursed upon receipt of appropriate documentation.

- STUDY START-UP FEE

A one-time, non-refundable Study Start-Up payment of Thirty Six Thousand Nine Hundred and Twenty Two Rupees (**INR 36,922**), will be made upon completion and receipt by Quintiles of all original contractual and regulatory documentation and receipt of an original invoice.

- Record Storage Fee/Archiving Fee

A record storage payment of Forty One Thousand Rupees **(INR 41,000),** will be made upon receipt of invoice and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all Site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

- Patient Travel Expenses

Patient travel expenses will be reimbursed upon receipt of original supporting invoices up to Eight Hundred Rupees (INR 800) per visit per patient per round trip and is included in the attached Budget. Invoices must contain the Patient number, amount paid, and visit number and visit date in which patient travel is being requested.

- **Meeting Attendance:**

Necessary travel and lodging expenses (including meals) incurred by the Site when attending Study start up meetings or other meetings necessary to provide information regarding the Study or Investigational Product will be reimbursed on a pass-through basis upon receipt of supporting invoices from a third party vendor.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

These amounts include all applicable taxes.

All payments for this Study in accordance with the attached budget will be paid by Quintiles by wire transfer.

K. BUDGET TABLE

Visit	Total Cost Per Visit With IOH & Travel
S1	26654
S2	24197
T1	14060
T2	10123
T3	11083
T4	11083
T5	3094
T6	11083
T7	3094
T8	11083
T9	3094
T10	11083
T11	3094
T12	11083
T13	3094
T14	11083
T15	3094
T16	11083
T17	3094
EOS	24405
PT1	3094
TOTAL	212855
Off Treatment scheduled Telephone Visit	544

*Treatment Telephone visits and in-clinic visits occurring beyond T17 will be reimbursed at the same rate as T16 and T17

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ATTACHMENT B
APPROVAL LETTER

ATTACHMENT C
EQUIPMENT (*optional*)

Sub Registrar
Jayanagar, Bangalore

DEPT. OF STAMP & REGISTRATION

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INDIA NON JUDICIAL GOVERNMENT OF KARNATAKA

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INVESTIGATOR CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" is made and entered into this **26th day of Sep, 2017** by and between

Biocad India Pvt. Ltd. Registered office address: #163/C, 3rd Cross, 3rd Phase, JP Nagar, Bangalore-560078, Karnataka, India., duly represented by Mr. Krishnamurthy Rao, Managing Director **(herein after referred to as "Biocad")**

AND

Dr Mahesh kumar V Kalloli, KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi -590010 Karnataka, India.(hereinafter referred to as the "**Principal Investigator**" or "**PI**")

AND

KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi -590010 Karnataka, India (hereinafter referred to as the **"Institution."**)

AND

Genesis Research, 4/22, Near Apoorva Hospital Jadhavwadi, Kolhapur, Maharashtra. India.

in connection with conduct of clinical trial - **"International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients"** bearing the protocol/study ID: BCD-021-02.

PI, Institution and Biocad hereinafter are individually referred to as "**the Party**" and are jointly referred to as "**the Parties**".

WHEREAS:

1. Sponsor is a pharmaceutical company responsible for execution of a clinical trial in **India.**

2. Biocad India is the Indian subsidiary of CJSC "BIOCAD" (Sponsor) which is a Russian biotechnology company, established in 2001. CJSC Biocad has both research and development and full cycle manufacturing facilities. Biocad India desires to engage the services of the PI to conduct/assist in this clinical trial ;

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3. PI has the necessary qualification, training, skill and facilities to conduct the clinical trial and is desirous of rendering such services upon such terms and conditions as envisaged below.

1. Provision of Services

1.1 The services to be provided by the PI to Biocad are described in detail in the statement attached hereto and incorporated herein by references as **Exhibit A** (hereinafter referred to as "**the Proposal**").

1.2 The Study will be conducted at the Institution under the supervision and direction of the Investigator, wherein Investigator shall control any individual performing any portion of the Study at the Institution. Site will carry out Study-related laboratory services and investigations as may be required for the Study.

1.3 The PI will conduct various activities with respect to the Clinical Trial (hereinafter referred to as "**activities**") in accordance with the following:

- Responsibilities of PI (attached herewith as **Exhibit A**) and Protocol of Clinical trial as amended from time to time.
- Budget (attached herewith as **Exhibit B)**
- All applicable International Conference on Harmonisation (ICH) Good Clinical Practice (hereinafter referred to as **"GCP"**) guidelines.
- All relevant current Indian Regulations and guidelines implemented or advised by the Indian Laws.

1.4 Biocad will provide the PI with all the information, documents, and materials which, in Biocad's reasonable opinion, are required in order to carry out activities in a Clinical Trial.

1.5 Biocad transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.6 Biocad will appoint a representative (hereinafter referred to as the **"Clinical Research Associate (CRA)/Clinical Research Monitor (CRM)"**) to be authorised to monitor the activities of the Clinical Trial. The CRA/CRM will coordinate performance of Clinical Trial with the PI. All communications between Biocad and the PI regarding the conduct of Clinical Trial shall be addressed to or routed through the CRA/CRM. Biocad may, at its discretion, change the CRA/CRM during the course of Clinical Trial and inform the PI accordingly.

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1.7 The PI will store copies of all data and records generated during the trial in accordance with local regulations, applicable GCP and as per the directions of Biocad.

2. Term

This Agreement shall commence on the date of execution and shall continue till the date of payment of the last sum due hereunder or till the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

3. Termination and Consequences of Termination

Termination:

3.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

3.2 Either Party may terminate this Agreement by written notice of **forty five (45) days** to the other Party without assigning any reason thereof and **with no penalty on either side**.

3.3 Either Party may terminate this Agreement by written notice of **thirty (30) days** in advance issued by means of communication ensuring evidence of the date of receipt in case of a substantial breach by the other Party of the obligations arising out of this Agreement, provided the Party receiving such notice has neither remedied nor sufficiently explained for the breach within the period specified in the notice.

3.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 3.3 above.

3.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

3.6 Upon expiry or termination of this Agreement, Biocad shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Biocad to the PI under this Agreement exceed the project costs as set forth in the study Budget.

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3.7 Upon expiry or termination of this Agreement, the PI shall, at Biocad' option, either immediately transfer to Biocad or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

4. Intellectual Property Ownership, Invention & Discoveries and Publication

4.1 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor (Biocad) which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor (Biocad).

4.2 The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the PI may publish data generated at their (own) site:

- only upon getting written approval from Sponsor and
- only after the first publication of such data by the Sponsor.

5. Representations; Indemnification

5.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

a. The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

b. All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

5.2 The PI will be covered by a professional indemnity of sufficient value as decided by Biocad, which shall be in force through out the term of this trial. However, this indemnity coverage does not cover any indemnity, liability or consequence arising out of or attributable to the negligence or willful misconduct of the PI.

6. Conflict of Interests

Site warrants that neither Institution nor Investigator has any conflict of interest that would affect the conduct of the Study. PI shall notify Biocad promptly and within twenty four (24) hours, if a conflict of interest arises during the term of this Agreement

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7. Payment

7.1 The total fees and expenses payable by Biocad to the PI for the services set forth herein shall not exceed the Budget as per **Exhibit B.**

7.2 This study is non-negotiable and includes all costs associated with the conduct of the study, including pharmacy fees, laboratory fees, dry ice, procedure cost, study coordinator/investigator fees, patient payments, all overhead charges and administrative fees.

7.3 Non Payment:
Unless and otherwise agreed in writing, Biocad India shall make no payment for patients whom the investigator entered into the study in violation of protocol (i.e, the patient is not a qualified participant)

7.4 Biocad shall pay the PI for same in accordance with the terms set forth herein after deducting there from any tax as applicable.

7.5 Payment shall be made by account payee Cheque / DD only.

8. Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

9. Arbitration

9.1 Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore.**

10. Force Majeure (Act of God)

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

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11. Record Keeping

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

12. Review of Work, Audit

12.1 The PI shall agree and permit concerned Government Agency, Regulatory Body, Sponsor Representative to perform, during normal business hours, quality assurance audits of the work performed under this Agreement to determine that the services are being performed in accordance with the applicable study Protocol, Government Regulations and this Agreement. PI promptly shall correct any errors or deficiencies discovered during an audit, under intimation to Biocad.

13. Headings

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

14. Notices & Service of documents

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Biocad shall be addressed to:

Biocad India Pvt. Ltd.
#163/C, 3rd Cross,
3rd Phase, JP Nagar,
Bangalore-560078
Phone No. 080-41699773
Fax No. 080-41699773

All the correspondence/ notices to be sent by Biocad to PI shall be addressed to:

Dr Maheshkumar V Kalloli,
KLES Dr Prabhakar Kore Hospital and MRC,
Nehru Nagar,
Belagavi -590010
Karnataka, India

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao **Managing Director** **Biocad India Private Limited**	**Genesis Research**	**Dr Maheshkumar Kalloli**	**Dr M.V Jali**
Seal: BIOCAD INDIA PVT. LTD. # 163/C, 3rd Cross, 3rd Phase, J.P. Nagar BANGALORE-78	**Seal:** GENESIS RESEARCH 4/22 Near Apoorva Hospital Jadhavwadi KOLHAPUR-416003	**Seal:** MAHESH KALLOLI M.C.Reg No. 71566 Consultant Surgical Oncologist KLES Dr Prabhakar Kore Hospital & MRC BELAGAVI	**Seal:** Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital Medical Research Centre, BELAGAVI
Witness	**Witness**	**Witness**	**Witness**

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Exhibit A

RESPONSIBILITIES OF PI:

INVESTIGATOR'S AGREEMENT FOR THE CLINICAL TRIAL - "International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients" bearing the protocol/study ID: **BCD-021-02**

1. I have sufficient time, adequate staff, and appropriate facilities to conduct and complete the Clinical Study. I agree to make these resources available for the duration of the study and agree that other Studies will not divert essential subjects or facilities away from this trial.

   I assure Biocad India Pvt. Ltd., that no other Clinical Study conducted by me shall give rise to a conflict of interest or interfere with the Clinical Trial.

   I will endeavor to ensure an adequate recruitment rate during the clinical investigation.

2. Biocad India Pvt. Ltd. will furnish me with copies of the Investigator's Brochure and the Study Plan or Protocol and I agree:

   a) to become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the pre-clinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and

   b) To become well acquainted with the Study Plan before signing it.

3. I agree to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the Study.

4. I understand that I shall have primary responsibility for the accuracy, legibility, and security of all Study data, documents, and subject records both during and after the Study. I will be responsible for signing the Case Report Forms (CRFs). Any alteration of the raw/source data shall be signed and dated, without obliterating the original entry.

   I agree to abide by the following conditions governing my handling of the data associated with this Study.

   a) I am required to maintain adequate records regarding all investigational product received and used by me including batch numbers, dates, and quantities. If the Study is terminated, suspended, discontinued, or completed, I

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shall return to Biocad India Pvt. Ltd., any unused supplies unless other arrangements are made by Biocad India Pvt. Ltd.

b. I am required to prepare and maintain adequate and accurate subjects, case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the Clinical Study.

c. I understand I am to furnish my records of the Study to Biocad India Pvt.Ltd.

d. I will maintain records of the disposition of the investigational product and other records for the duration longer than the following periods:

i. the period defined by national or local law and rules
ii. five years after the Study is terminated or computed, or
iii. five years after the records are no longer required for purposes of supporting the relevant United States, other national, European (EU), or other international regulatory applications.
iv. To avoid any possible errors I will contact Biocad India Pvt. Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e. I agree to provide accurate information to the Ethics Committee upon request. I also agree to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies' authorities and my ethical obligations, as set forth below:

1. Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, I will make records related to the Clinical Study available for inspection and copying.

2. The subject's identity will not be released except under the following limited circumstances.

i) Where data verification procedures demand inspection of subject's personal identity or personal medical information, in which case this inspection may be performed only by a properly authorized person.

3. The subject's identity shall not be released to third parties without the Subject's or subject's legal representative's prior consent. Accordingly, the study subject's or subject's legal representative's consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

5. I agree to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Biocad India Pvt. Ltd.

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I shall not commence the Study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject recruitment procedures, and any written material to be provided to the subject or the Subject's legal representative.

I shall provide the Ethics Committee or Institutional Review Board with all required information.

6. I certify that the investigational products for clinical investigation will be provided only to subjects under my personal supervision or under the supervision of the following sub-investigators responsible to me (add any additional names on a separate sheet, if needed):

Sub-Investigator 1: Dr Jyothi Hattiholi

I further certify that the investigational products will not be supplied by me to any investigator, other than those listed above as sub-investigators, or to any clinic, medical facility, or study site for use.

7. No procedure will be performed until all personnel have been properly trained.

8. I agree to be responsible for the personal safety and well being of the subjects. To this end, I agree to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:

Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature.

a) I will ensure that subject / subject's legal representative or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the subject / subject's legal representative.

The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.

b) I will ensure that the subject / subject's legal representatives are given the opportunity to inquire about the details of the Clinical Study. The information given to the subject /subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the Clinical Study at any time without any sanction. I will make an effort to ascertain the reasons for any withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.

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c) I will ensure that the subject / the subject's legal representatives are provided adequate time to decide whether or not they wish to participate / wish their ward to participate in this clinical investigation.

9. I will ensure that complete Case Report Forms (CRF) provided by Biocad will be completed promptly and accurately within 5 working days after the visit occurs at site and also ensure that any queries arising will be resolved within 3 working days.

10. I will discuss with Biocad India Pvt. Ltd. any question of modification of the Study Plan and obtain Biocad India Pvt. Ltd. written agreement and also approval from the ethics committee prior to implementation of any modification. I will not precede with a non-emergency deviation from the Clinical Protocol without approval from Biocad India Pvt. Ltd. and as needed the Ethics Committee. It is my responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by Biocad India Pvt. Ltd., including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

11. I will report all adverse events to Biocad.

a. I will promptly report:
   - Deviations from or changes to the protocol to eliminate immediate hazards to the study subjects.
   - Changes increasing the risk to subjects and/or affecting significantly the conduct of the study.
   - All adverse drug reactions (ADRs) and Adverse Events (AEs) that is both serious and unexpected.
   - New information that may affect adversely the safety of the subjects or the conduct of the study.

b. All staff in contact with the subject should be aware of their responsibility to note and report all adverse events reported by the Subjects / subjects legally acceptable representative.

c. The Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d. All serious adverse events (SAEs) should be reported to Biocad within 24 hours.

e. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

f. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the study subjects rather than by the subjects' names, personal identification numbers and/or addresses.

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g. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to Biocad according to the reporting requirements and within the time periods specified by Sponsor in the Protocol.

h. I will personally be responsible for, or I will appoint a sub-investigator (who has signed an Investigator Agreement and has been added to the Institution's, Biocad India Pvt. Ltd. and the Study Monitor's Investigator List) to be responsible for all Study related medical decisions.

i. I agree to personally conduct and/or supervise the clinical trial at my site. I may delegate some of the activities to the study staff, However all delegated activities will be my responsibility.

12. I will report all deviations from the protocol to Biocad India Pvt. Ltd. and the study monitor.

13. I will notify Biocad India Pvt. Ltd., immediately, but in no event in more **than five working days**, about withdrawal of approval by the reviewing Ethics Committee of my part of the Clinical Study.

14. I will comply with any request by Biocad India Pvt. Ltd. to return or dispose off, investigational product (IP) upon termination or completion of the clinical study. I understand that Biocad India Pvt. Ltd. is required by law to discontinue shipments of investigational product to me if I fail to comply with the Study Protocol or with any applicable laws or regulatory requirements applicable to the investigation, including national guidelines.

15. I agree to permit personnel from Biocad India Pvt. Ltd. and/or the Study Monitor/auditor to visit me and/or the Study Site to monitor my compliance with the protocol and/or audit the investigational records. To facilitate Biocad India Pvt. Ltd., or the Study Monitor's audit, I further agree to make records related to the Clinical Study available for inspection and copying.

16. I agree to maintain confidentiality regarding all information generated in the course of this Clinical Study. I further agree to ensure that the confidentiality of all information about subjects and the information supplied by Sponsor is respected by all persons, with the limitations discussed above.

17. I agree to submit and sign a Final Report of the Clinical Study within three months after termination or completion of the Clinical Study or of my part in the Clinical Study to the Ethics Committee.

I agree to abide by this Investigator Agreement.

Investigator Signature: _____

Date Signed: 4 Oct 2017

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Exhibit B: Proposal (Budget)

Budget and Payment Terms

1. All payments would be made only upon fulfilment of responsibilities by the PI as described in Exhibit A and the services provided by the PI as is described in the clinical trial protocol including its amendments.

2. Biocad India Pvt. Ltd. offers to pay the PI **Rs.3,50,250 which** will be paid per subject as per Annexure I who completes full study (complete all study visits and procedures as required by the protocol)
   This payment is inclusive of all patient related cost as well as non patient related cost such as all Overhead expenses, completion of case report forms, audits, Hospitalization and infusion charges, pharmacy fees and lab costs for testing {for example CBC, ECG, USG, CT Scan(contrast), Biopsies, as per protocol requirement}, patient travel costs, including unscheduled visits as per protocol, study/site staff fees. (Subject to deductions as per point No.4 below):

3. For Screening Failure, Rs. 9000 per patient (Investigations are reimbursed as per actuals) will be paid to PI which includes institutional overhead charges.

   Reimbursement will be not be made for any additional testing, treatment or procedures not required by the protocol, unless such additional testing, treatment or procedures are pre-approved by the sponsor.

Terms of Payment:

- Payment will be made after verifying completed case report forms and completion of Resolution of Data Clarification Form/ Data queries raised by Data Management for that respective visit.

- In case the patient does not complete the milestone visits then the payment would be made as per the earliest milestone visit.

- Payment to the PI on the above milestones will be made on monthly basis only by a crossed A/C Payee Cheque in favour of Genesis Research. No payment shall be made in cash.

- The final payment will be subject to a final reconciliation, meaning after (i) all subjects have completed the study, and the database has locked, (ii) all study specific queries and issues (including data queries) has been satisfactorily resolved. (iii) The site close out visit has been completed (including the return of all study drugs) and (iv) Study records have been received by sponsor.

4. The following deductions will be made, if applicable:
   - Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.

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- Any capital expenses for the site incurred by Biocad on behalf of PI will be deducted from the fee payable to PI.

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Seal:	**Seal**	**Seal**	**Seal:**
Witness	**Witness**	**Witness**	**Witness**

Dr. MAHESH KALLOLI
KMC Reg. No. 71566
Consultant Surgical Oncologist
Dr. Prabhakar Kore Hospital
BELAGAVI

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI

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Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the 30th day of Oct 2017 between **1) Dr. Jyothi Hatthioli ("Investigator"), Consultant Pulmonologist at KLE's Dr. Prabhakar Kore Hospital** and **2) KLE's Dr. Prabhakar Kore Hospital ("Institution")** both having its address at **KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India 3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.**; through its **Clinical Research Business ("Reliance")**, with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

"Investigator", "Institution", "SMO" and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	RLS/RES/2016/01
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022 / Xolair® in patients with moderate to severe persistent asthma.
STUDY PRODUCT:	*R-TPR-022 / Xolair®*
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Jyothi Hatthioli**
INSTITUTION/SITE:	**KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Clinical Research Business of Reliance Life Sciences is involved in clinical trials management and related clinical development activities;

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/RES/2016/01** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

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WHEREAS the Institution has engaged **Genesis Research** a Site Management Organization of **KLE's Dr. Prabhakar Kore Hospital & M.R.C.**, authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

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d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 Site Visits. The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product.

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

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c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 **New findings.** Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization**:

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

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including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

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transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator, SMO and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator, SMO and Institution during the course of the that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to the Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification number(s) and / or addresses.

The Investigator shall retain the Records of the Study, including either the original of all volunteer consent forms, for the longer of:

(i) two (2) years after the date of the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region for the Study Product in the indication being investigated.

(ii) two (2) years after the Investigator is notified by Sponsor that the clinical development of the Study Product has been formally discontinued; and

(iii) as may be required under the applicable Indian laws and regulations.

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or SMO or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution//Investigator, and Institution//Investigator shall comply with Sponsor's directions.

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7. **Publication.** The results of the Study including all obtained data will be the property of the Sponsor. The Investigator, SMO and Institution should not publish or communicate the data in public without written authorisation by the Reliance Unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of the Sponsor. The Investigator and /or Institution and/or SMO may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by the Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action; however, any delay in publication shall not exceed one hundred and twenty (120) days after Investigator takes the requested action.

8. **Subject Injury Reimbursement**

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor agrees to reimburse Institution and/or Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Trial Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 122 DAB of Drugs and Cosmetics Rules 1945 in case of Trial Subject's injury and/or death. Institution and Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Institution, SMO and Investigator further agree to promptly notify Sponsor of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

9. **Inspection and Debarment.**

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from

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time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:
   i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or
   ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

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iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. **Indemnification; Claims and Disclaimers.**

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11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or
(iii)any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or
(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.
c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and
d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and
e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

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11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. Financial Disclosure. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

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13. **Insurance**: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 **Solicitation of subject:** Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 **Press Releases**: Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 **Enquiries from media and financial analysts**: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 **Use of Name**: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 **Additional Contractual Provisions.**

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

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16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and

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Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 30 Oct 2017

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Jyothi Hatthioli

Title: Consultant Pulmonologist

Date: 4th Nov 2017

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: Dr. M. V. Jali.

Title: KLE's Dr. Prabhakar Kore Hospital & M.R.C.

Date: 11 Nov 2017

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 14 Nov 2017

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Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	**Genesis Research**
PAYEE ADDRESS:	**4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**CQJPP0528D**
GSTIN	**27CQJPP0528D1ZX**

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research** in Indian Rupees.

The Parties agree that the payee designated herein is the proper payee for this Agreement, and that payments under this Agreement will be made only to the designated payee ("Payee").

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory

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documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

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Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: **RLS/RES/2016/01**

Investigational Product: R-TPR-022

Clinical Trial Budget		
	Project Name:	Omalizumab
	Project Code	K068
	Name of PI	Dr. Jyothi
		Unit Cost/Visit
Investigator fees		
	Principal Investigator	4,000
	Clinical Research Coordinator	1,200
	Unblinded Pharmacist	300
	Phlebotomist	200
Patient related expenses		
	Travel reimbursement	300
	Hospitalization charges	10,000
	Consumables	100
Administrative overhead-20%		1,040
Laboratory Testing Charges		
	Name	Cost
	Investigation	
1	Skin Prick test	450
2	Lung Function Test	800
3	12 lead ECG	350
4	Chest X Ray	500
Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study. Skin Prick Test Charges are per patient and kits will be provided by Reliance		

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er Visit Payment schedule:

Budget for 2 weekly dosing schedule						
Visit	Sub visit	Investigator fees	Laboratory Test	Patient related expenses	Administrative Overheads	TOTAL
Screening		5200	2100	300	1040	8640
Day 0/Week 1	0 hrs	5700	800	10400	1140	18040
	12hrs	200	0	0	40	240
	24 hrs	200	0	0	40	240
Day 2	48 hrs	200	0	300	40	540
Day 3	72 hrs	200	0	300	40	540
Day 4	96 hrs	200	0	300	40	540
Day 5	120 hrs	200	0	300	40	540
Day 7	168 hrs	200	0	300	40	540
Day 9	216 hrs	200	0	300	40	540
Day 12	288 hrs	200	0	300	40	540
Day 15	360 hrs	200	0	300	40	540
Day 22	528 hrs	200	0	300	40	540
Day 30	720 hrs	200	0	300	40	540
Week 2		5700	800	400	1140	8040
Week 4		5700	800	400	1140	8040
Week 6		5700	800	400	1140	8040
Week 8		5700	1150	400	1140	8390
Week 10		5700	800	400	1140	8040
Week 12		5700	800	400	1140	8040
Week 14		5700	800	400	1140	8040
Week 16		5700	1150	400	1140	8390
Week 18		5500	800	400	1100	7800
Week 20		5500	800	400	1100	7800
Week 22		5500	800	400	1100	7800
Week 24		5500	1150	400	1100	8150
Week 26		5500	1150	400	1100	8150
TOTAL		86400	14700	18900	17280	137280
					CGST (9%)	0
					SGST (9%)	0
					IGST (18%)	24710
					Total budget per subject	161990

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Budget for 4 weekly dosing schedule						
Visit	**Sub visit**	**Investigator fees**	**Laboratory Tests**	**Patient related expenses**	**Administrative Overheads**	**TOTAL**
Screening		5000	2100	300	1040	**8440**
Day 0/Week 1	0 hrs	5600	800	11200	1140	**18740**
	12hrs	200	0	0	40	**240**
	24 hrs	200	0	0	40	**240**
Day 2	48 hrs	200	0	300	40	**540**
Day 3	72 hrs	200	0	300	40	**540**
Day 4	96 hrs	200	0	300	40	**540**
Day 5	120 hrs	200	0	300	40	**540**
Day 7	168 hrs	200	0	300	40	**540**
Day 9	216 hrs	200	0	300	40	**540**
Day 12	288 hrs	200	0	300	40	**540**
Day 15	360 hrs	200	0	300	40	**540**
Day 22	528 hrs	200	0	300	40	**540**
Day 30	720 hrs	200	0	300	40	**540**
Week 4		5600	800	400	1140	**7940**
Week 8		5600	1150	400	1140	**8290**
Week 12		5600	800	400	1140	**7940**
Week 16		5600	1150	400	1140	**8290**
Week 20		5400	800	400	1100	**7700**
Week 24		5400	1150	400	1100	**8050**
Week 26		5400	1150	400	1100	**8050**
Total		**51600**	**9900**	**17300**	**10520**	**89320**
					CGST (9%)	**0**
					SGST (9%)	**0**
					IGST (18%)	**16078**
					Total budget per subject	**105398**

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: R-TPR-022
I No: RLS/RES/2016/01

Note:

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- # In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll 10 patients. The payment schedule would be done as per the actual dosing regimen only i.e.02 weekly or 04 weekly to maximum of INR 161990 only.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

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CLINICAL TRIAL AGREEMENT

PROTOCOL:

Multicenter, Open-Label, Randomized, Prospective Phase IV, Interventional, Non-Inferiority Study with Blinded Assessment, to Evaluate the Efficacy and Safety of Fixed Dose Combination (FDC) of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) in Adult Indian Patients who have HIV-1 Infection

This Clinical Trial Agreement (the **"Agreement"**) is effective on the date fully executed by the parties (the **"Effective Date"**) and entered into by and between:

ECRON ACUNOVA LIMITED (FORMERLY KNOWN AS MANIPAL ACUNOVA LIMITED), a company incorporated under the Companies Act, 1956 having its Registered Office at Mobius Towers, SJR i-Park, EPIP, Whitefield, Bangalore – 560 066, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Dr. Dnyanesh N Morkar, the **Principal Investigator** presently employed at **KLEs Dr Prabhakar Kore Hospital and MRC** (hereinafter referred to as the "Principal Investigator" which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

KLEs Dr Prabhakar Kore Hospital and MRC situated at **Nehru Nagar, Belagavi - 590010**(hereinafter referred to as the "Institution" which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

AND

Genesis Research situated at **4/22, Near Apporva Hospital, Jadhavwadi, Kolhapur -416005** (hereinafter referred to as the "SMO" which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

CRO, Principal Investigator, Institute and SMO are referred to herein individually as a "Party" and collectively as "Parties".

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Whereas, **Mylan Pharmaceuticals Private Limited (MPPL)** (hereinafter referred to as the **"Sponsor"**) through its representative CRO desires the Institution to study Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study with the responsibility for the proper conduct of the Study (defined herein below);

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. THE STUDY AND THE PROTOCOL

The study of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) (the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No MYL -TLE 400 - 4001and entitled "Multicenter, Open-Label, Randomized, Prospective Phase IV, Interventional, Non-Inferiority Study with Blinded Assessment, to Evaluate the Efficacy and Safety of Fixed Dose Combination (FDC) of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) in Adult Indian Patients who have HIV-1Infection" a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored by the CRO as per the Protocol.

A. The Principal Investigator represents and warrants that he is qualified by education, training and experience to assume responsibility for the proper conduct of the Study. The Principal Investigator will provide a copy of the curriculum vitae and other relevant documents requested by the Sponsor, the Ethics Committee, CRO and the Regulatory Authorities. Principal Investigator clearly understands that time is of the essence of this Agreement and will ensure that other resource demands of the Study will be fulfilled throughout the duration of the Study. The Principal Investigator should also ensure that he does not have any conflict with any other studies and shall not divert Subjects or facilities away from the Study. Principal Investigator confirms that he/she has the necessary experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol. The Principal Investigator shall be responsible for performing the Study in strict compliance with the specifications and timelines provided by CRO.

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B. The Institution represents and warrants that it has the necessary infrastructure, experience and expertise to conduct the Study in accordance with the terms of this Agreement and that the Institution will use all commercially reasonable best efforts to perform efficiently the Study services hereunder. The Study will be conducted at Institution and will be supervised by the Principal Investigator, wherein Principal Investigator shall control any person performing any portion of the Study at the Institution and Principal Investigator. Institution and Principal Investigator will carry out certain Study-related laboratory services and investigations as may be required for the Study. In any event, if the Principal Investigator is unable to perform the obligations of Study or suspends or abandons or is unwilling to continue with the Study, CRO and Institution shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, in such case, the Study may be terminated at the option of the CRO for andon behalf of the Sponsor or by the Sponsor.

C. **Conditions precedent.** The Principal Investigator shall be thoroughly familiar with the safety, efficacy and appropriate use of the Study Drug as described in the Protocol, the Reference-listed Product with full prescribing information, and other information sources relevant to the Study and as may be provided by the Sponsor from time to time. The Study shall take place at the Site under the supervision and direction of the Principal Investigator, who will be the Principal Investigator for the Study.

D. The Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. CRO, Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Institutional Ethics Committee) or IRB (Institutional Review Board)

2. THE STUDY SCHEDULE

A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest time after receiving the applicable regulatory / IEC / IRB approvals.

B. **Enrollment.** Principal Investigator shall be responsible for recruiting eligible Subjects to the Study. Principal Investigator shall use the best efforts to recruit the Subjects and ensure unbiased selection of suitable Subjects in accordance with the terms of Protocol. Principal Investigator will enroll minimum 10-12 Subjects (as per the randomization schedule) and not more than 40-50 Subjects (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the CRO. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the CRO, or the Sponsor's designee, that, in the sole determination of the CRO:

i. the Complete Study enrollment has been achieved; or

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ii. the CRO and Sponsor have placed the Study on hold, for any reason; or

iii. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

Notwithstanding anything contained herein, Institution and Principal Investigator shall adhere to the strict principles of confidentiality under Applicable Laws and Requirements and protect such personal data of Subjects including privacy laws as may be applicable thereon.

C. Study Documentation. Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three to five (3 to 5) working days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three to five (3 to 5) working days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three to five (3 to 5) working days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the CRO and Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. There will be no paper Data Clarification Forms Queries ("DCFs"). Site staff will have to enter the eCRF and resolve the same within **three (3) working days** of its receipt. Only in case of urgent requirement of safety data, safety vendor may contact the site to request the safety data which should be contacted as early as possible.

D. Subject Samples. All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals and applicable law.

Study Completion. The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than five days after the last Subject visit. In any event, Institution and Principal Investigator shall not publish or present interim or preliminary results of the Study at any time without the prior written approval of CRO and Sponsor.

3. PAYMENT

A. Budget and Payment Schedule: In consideration of the Services performed, CRO shall reimburse the Institution all undisputed direct and indirect costs reasonably incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by cheque. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study. Notwithstanding the Payment Schedule mentioned in Exhibit B, the payment made by CRO shall be deemed to be as full and final payment payable by CRO as consideration for the services provided by Site including Principal Investigator, Institution and SMO.

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B. Payment of Costs outside Budget and Payment Schedule. Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. Payment Terms. CRO shall have no obligation to make payments for any subject who is not qualified to participate in the Protocol based on the inclusion and exclusion criteria described in the Protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the CRO and Sponsor's clinical and/or medical monitor identified in the Protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. Payment Recipient and Mailing Address. All cheques shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

The further details for the payments should be provided as

1. **Cheque in the favor of: Genesis Research**
2. **PAN Number: CQJPP0528D**
3. **Name of Bank: State Bank of India**
4. **Branch: Market Yard, Kolhapur**
5. **Account No: 36599680134**
6. **Branch Code: 001887**
7. **IFS CODE : SBIN0001887**

E. Reimbursement. Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

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F. Payments for Screen Failure: CRO shall pay only per Subject charges for screen failure. The maximum ratio for screen failure Subjects shall be 5:1 i.e. maximum one screen failure per five randomized Subjects.

G. Payment for Study Coordinator: PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

H. All payments payable by CRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site. Goods and Service Tax (GST) will be paid, if applicable, on generation of valid tax invoice showing the amount of GST to be charged before any payment is made under this Agreement

The parties acknowledge that the designated Payee is authorized to receive all the payments for the services performed under this Agreement. Investigator acknowledges that if Investigator is not the Payee, CRO will not pay Investigator even if the Payee fails to reimburse Investigator.

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

A. IEC/IRB Approval. The Principal Investigator shall be responsible, with the cooperation of the Institution and CRO/Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the CRO or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notified by the Sponsor or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. Performance of the Study. The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study: Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC/IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this

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Agreement to any other individual or entity without the prior written consent of the CRO. The Principal Investigator shall be responsible for responding promptly, in writing, to all issues and questions raised by regulatory agencies relating to the performance of the Study

C. Patient consent and entry into Trial. As well as complying with the requirements of the Declaration of Helsinki, the principles of Good Clinical Practice [and other legislation appropriate to clinical trials, medical treatment, and the processing of personal and medical data], the Investigator shall, before entering a patient into the Trial:

i. exercise independent medical judgement as to the compatibility of each prospective Patient with the requirements of the Protocol;

ii. advise the CRO of all instances in which, in the Investigator's judgement, there is any question as to any prospective Patient's suitability for participation in the Trial, and abide by the Sponsor's decision as to whether or not to enrol that Patient;

iii. ensure that, before their participation in the Trial, the Patients are duly informed about all aspects of the Trial that are relevant to them, including:

iv. the purpose, duration, nature, significance, implications, and risks of the Trial; and

v. the processing, auditing, and monitoring of data (including personal data) under this Agreement.

vi. ensure that, before his or her participation in the Trial, each Patient has given his or her Informed Consent on the basis of the information described in Clause 2.5(c) by signing a consent form in accordance with the Protocol;

vii. acknowledge that the use of the consent form does not release the Investigator from his or her legal and contractual obligations relating to Informed Consent, and that it remains the Investigator's responsibility to ensure that those obligations are complied with;

viii. comply with the procedures described in the Protocol in relation to that Patient; and

ix. provide details of the proposed Patient to the CRO.

D. Key Personnel. The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the CRO and/or Sponsor's designee and the CRO and/or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the CRO may terminate this Agreement as set forth in Clause 12(B) below.

E. Sponsor Visits. The Sponsor's representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and

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the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. Supplies.

a. The Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug hereunder, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

G. Study Records, Reports, and Data.

i. *Study Records.* The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice

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("**Study Records**"). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of seven (7) years after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ Sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the Study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data. In no event, shall Institute and Principal Investigator remove any Study Records or destroy any Study Records without the prior written consent of CRO and Sponsor.

ii. *Case Report Forms.* The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement.

iii. *Annual Reports.* The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC/IRB.

iv. *Final Reports.* Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome ("**Final Report**") to the IEC/IRB. In addition, any Serious Adverse Events will be reported to the IEC/IRB.

v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of Study Records.Sponsor and CRO will help to find vendor for archival of study records.

H. **Reporting of Serious Adverse Event.**

- In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

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- In the event of a trial related injury or death, CRO (as a representative of the sponsor) on behalf of Sponsor shall provide financial compensation for the injury or death.

- Neither CRO nor Sponsor will be responsible for, and Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any loss, damage, liability, claim, cost (including reasonable attorney fees) or demand arising from any injuries or damages resulting from negligence, failure to adhere to the Protocol, failure to comply with Applicable Laws, failure to obtain informed consent, unauthorized warranties made by, breach of this Agreement or willful misconduct or omission of Site or any Site Personnel in performing their obligations under this Agreement.

- Sponsor will promptly inform Site, Site's Institutional Review Board/EC, and CRO, of any finding that could affect the safety of subjects or their willingness to continue participation in the Study, influence the conduct of the Study, or alter Site's IRB/EC approval to continue the Study. Site shall promptly, in accordance with Applicable Laws, advise Sponsor and CRO of any Adverse Event occurring during the conduct of the Study that it becomes aware of. In the event of the occurrence of any serious Adverse Event, Site shall notify CRO and Sponsor or its designee by fax and/or other electronic means within twenty-four (24) hours of the occurrence.

- The recording of Adverse Events is an important aspect of study documentation. It is the Investigator's responsibility to document all Adverse Events according to the detailed guidelines of the Protocol. The Investigator agrees to answer any questions of Sponsor/CRO's medical monitor concerning any Adverse Events.

- The Investigator must immediately report all Serious Adverse Events ("SAE") (as defined in the Protocol) (within 24 hours of occurrence of SAE) to the DCG (I), Sponsor and Ethics Committee which occur since informed consent is signed, during the course of the Study and up to the date of the subject's last visit.

- The Investigator shall forward a due analysis report to DCG (I), Ethics Committee and Head of the Institute within fourteen (14) days of occurrence of SAE including all initial information and follow-up information until stabilization/ resolution of the SAE.

5. CONFIDENTIALITY

A. **Confidential Information.** The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution, SMO or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution, SMO or the Principal Investigator as required by the Protocol

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and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

i. Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;

ii. Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;

iii. Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and

iv. Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

Disclosing Party: The term "Disclosing Party" shall mean the Party disclosing Confidential Information to other Party.

Receiving Party: The term "Receiving Party" shall mean the Party receiving Confidential Information from the other Party.

All Confidential information shared hereunder for purpose of completion of Study and who are legally bound by confidentiality and non-use obligations, no less restrictive than those contained in this Agreement and any other confidentiality agreement executed. In addition, Institution, Principal Investigator and Site shall not use any Confidential Information for any purpose other than the conduct of the Study and shall ensure that the co-investigator who has access to Confidential Information is informed of its confidential nature and agrees to comply with the obligations of confidentiality and non-use, as set out in this Agreement and any other confidentiality agreement executed.

In addition to any other rights and obligations contained herein or elsewhere in the Agreement, Sponsor, or CRO on Sponsor's behalf, shall be entitled to seek an injunction from a court of competent jurisdiction for the purpose of preventing any existing or anticipated breach of the terms of confidentiality under this Agreement.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution, Principal Investigator or SMO from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution,Principal Investigator or SMOfurnish at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution, Principal Investigator or SMO or to adequately demonstrate to the Institution,Principal Investigator or SMOthat it has complied with all applicable disclosure

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requirements, or (ii) prevent Institution, SMO and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. Non-Disclosure and Non-Use. Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of ten (10) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. Medical Confidentiality. Notwithstanding any of the foregoing, Sponsor and CRO shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access to in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws.

E. The PI and Institution hereby acknowledge and agree that in accordance with the applicable laws and codes, and in particular with any transparency obligations contained therein, certain value transfers between pharmaceutical companies and healthcare professionals and/or healthcare or academic institutions or hospitals, are subject to mandatory publication. The Parties acknowledge that, in accordance with said obligations the Sponsor is responsible for the publication of the relevant information in the appropriate format and within the applicable timeframe. Such information shall at least include the amount, purpose and recipient of the value transfers. The PI and Institution hereby explicitly agree with such publication by Sponsor, provided the publication is in accordance and strictly limited to the requirements of the said laws and codes, and does not go beyond the requirements of the applicable privacy laws.

6. Protection. Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure

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or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. PUBLICATION

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish information arising from his/her participation in the Study, the prior written approval from Sponsor is required.

8. OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES

A. Materials and Data. The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA, DCGI or other regulatory agencies.

B. Patents and Inventions.

i. All right, title and interest in and to, whether domestic or foreign, any inventions or discoveries (collectively, **"Inventions"**) first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in Protocols, lab notebooks, or other written records, the know-how incidental thereto, and any patent applications and resulting patents derived there from shall be the exclusive property of that Party.

ii. "New Invention or Discovery" shall mean any invention or discovery conceived and reduced to practice during and as a part of Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of the Sponsor.

iii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor. Institution and Principal Investigator shall assign and transfer to Sponsor without further consideration, the

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entire right, title and interest globally in all Sponsor Intellectual Property of any New Inventions made or any process carried out in the name of Sponsor. Institution and Principal Investigator acknowledge that all original works of authorship made whether by Institution and Principal Investigator under this Agreement are "works made for hire" and assist Sponsor in obtaining patent or other intellectual property protection.

iv. New Inventions or Discoveries arising out of the research performed under this Agreement solely by Institution, Principal Investigator, and/or any of their respective agents that is not covered by the provisions of Clause 7(B)(*iii*) (an **"Institution Invention"**) shall be the sole property of Institution (subject to any agreement between the Institution and Principal Investigator regarding the ownership of inventions).

v. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. No Other Rights. Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

A. Of the Principal Investigator. The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the CRO (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol

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criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable law relating to clinical studies that has not been disclosed to the CRO and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation (**"Notice of Intent to Disqualify"**). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the CRO with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the CRO shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the CRO immediately and the CRO shall have the right to terminate this Agreement immediately without further cost or liability.

B. <u>Of the CRO.</u> The CRO represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the CRO's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms. CRO represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) CRO has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration of drugs and devices

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under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular CRO shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

C. No Other Representations or Warranties. Except for the limited representations and warranties given in this Clause 9, none of the Sponsor, the CRO, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

D. Of the Institution: Institution will ensure that the Principal Investigator remits to the Sponsor all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the CRO and Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

10. GOVERNING LAW

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Bangalore, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the courts of Bangalore, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Bangalore, India.

11. INDEMNIFICATION

A. CRO Indemnification.The CRO shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents harmless against all notices, claims, demands, action, suits or proceedings given, made or initiated against the CRO due to a) Breach of responsibility of the CRO; b) Willful negligence; c) Willfulmisconduct or misrepresentation d) breach of representation and warranties and confidentiality obligations under this Agreement (e) CRO's Negligence (f) Breach of Applicable Law.

B. Institution Indemnification. The Institution shall defend, indemnify, and hold harmless the CRO/Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("**CRO Indemnities**") from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the CRO Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the CRO concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner

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required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnitee, or any other person on the Institution's property or under its control, exclusive of the CRO's employees and (iii) (a) breach of any terms of the Agreement and the representations and warranties made by Principal Investigator or Institution jointly and / or severally.

C. **Notification.** The Parties shall promptly notify each other of any such claims, suits, actions, demands, or judgments and the Parties shall reasonably cooperate with each other in the handling thereof.

D. **Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

E. **Representation.** In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnitee.

F. **Subject Injury.** Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the CRO in case of Subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

12. INSURANCE

A. Parties represent and warrant that they possess and shall maintain, for the duration of the Agreement and thereafter, at its own expenses, insurance coverage for their respective services in the performance of the Study. Each Party shall provide the other Party with proof of insurance upon request.

B. **Institution Insurance.** Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 12 shall survive termination of this Agreement.

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13. TERM AND TERMINATION

A. Term. This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F) (*iv*), above, unless earlier terminated in accordance with this Agreement.

B. Termination.

i. Either Party may terminate this Agreement immediately upon written notice to the other if:

b. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;

c. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

d. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement..

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

iv. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, CRO will make payment to Institution for:

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. Reasonable non-cancelable obligations (as evidenced in writing) properly incurred for the Study by Institution prior to the effective date of termination.

v. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by CRO, to the extent medically permissible.

vi. Immediate Termination by the CRO/Sponsor. The CRO/Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.

vii. Effect of Termination. In the event this Agreement is expired or terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the

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IRB/IEC that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the CRO to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the CRO's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes and shall make no further use of, all Sponsor Confidential Information, and any other records, data, materials and information that are the property of Sponsor. The CRO shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement. Notwithstanding any termination or expiration of the Study or this Agreement, Institution shall remain responsible for compliance with all obligations under Applicable Laws and other requirements as per this Agreement with regards to disposition of the Study Materials.

viii. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11,and 12 shall survive any termination of this Agreement for any reason.

14. **Drug Safety and Reporting.** The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of Sponsor and/or CRO's Medical Monitor concerning any AEs. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.

Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR

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If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of the Study, or could alter the ECs / IRB's approval to continue the Study.

CRO will be responsible to notify on time the health authorities in India.

15. MISCELLANEOUS

A. **Use of Names; Publicity**. Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its staff/employees, agents in any advertisement or sales promotional material or in any publication, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Section 7 herein). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement even existence of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances and ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. **Independent Contractors**. The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and shall not to be considered as partner, agent, employee, or representative of CRO or the Sponsor. That neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. **Limitation of Liability.** In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.CRO expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product.

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D. Notices. Any notices required or permitted to be given hereunder shall be in writing, shall be addressed to the Party to whom such notice is intended as follows, or such other address and/or number as such Party may substitute by written notice hereunder, and shall be effective on receipt.

Any notice to Sponsor shall be addressed as follows:

Address	: **Mylan Pharmaceutical Private Limited, 7th-12th Floor, Prestige Platina Tech Park, Block 3, Kadubeesanahalli, Outer Ring Road, Bangalore-560087**
Attention	: **Dr Sanjeev Hegde**
Title	: **Associate Vice President**
Phone	: **+91 7349635726**
Fax	: **NA**

Any notice to Institution shall be addressed as follows:

Address	: **KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi 590010**
Attention	: **Dr M.V. Jali**
Title	: **Head of the Institution**
Phone	: **+91 9844032499**
Fax	: **+91 8312470732**

Any notice to Principal Investigator shall be addressed as follows:

Address	: **KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi. 590010**
Attention	: **Dr Dnyanesh N Morkar**
Title	: **Principal Investigator**
Phone	: **+91 9448231298**
Fax	: **+918312493099**

Any notice to SMO shall be addressed as follows:

Address	: **4/22, Near Apporva Hospital, Jadhavwadi, Kolhapur -416005**
Attention	: **Mr. Satyajit Patil**
Title	: **Manager**
Phone	: **+91 9762881140**
Fax	: **NA**

Any notice to CRO shall be addressed as follows:

Name of CRO	: **Ecron Acunova Limited (Formerly known as Manipal Acunova Limited)**
Address	: **Mobius Tower, SJR- I Park, EPIP, Whitefield, Bangalore-560066**
Attention	: **Dr. Ayaaz Hussain Khan**
Title	: **Managing Director**
Phone	: **080 6691 5700**

ECRON ACUNOVA LTD. Bangalore

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E. Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. The Sponsor may assign this Agreement to any successor to all or substantially all of the business of the Sponsor, or in connection with its merger, consolidation, change in control or similar transaction. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.

F. Modification; Waiver. This Agreement may not be altered, amended or modified in any way except in writing signed by the CRO, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right. Parties shall not delegate or subcontract its duties under this Agreement without prior written consent of the CRO/Sponsor

G. Entire Agreement. This Agreement and its Exhibits constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior discussions, negotiations, communications, understandings, agreements, representations and writings with respect to all matters covered by the Agreement. In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence except as otherwise specifically set forth in this Agreement.

H. Severability. In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

I. Execution. The Institution's IRB/IEC shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile or other electronic signature.

J. Changes to the Protocol. If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

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K. Covenant Not to Hire. Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

FOR AND ON BEHALF OF INSTITUTE
By:

(Signature and Date)

NAME: DR M.V. JALI

FOR AND ON BEHALF OF SMO
By:

(Signature and Date)

NAME: MR. SATYAJEET PATIL

FOR AND ON BEHALF OF
ECRON ACUNOVA LIMITED
(FORMERLY KNOWN AS MANIPAL ACUNOVA LIMITED)

By: 27 Dec 2017
(Signature and Date)

DR. NAGESWARI SANTOSH
NAME:

AND

By: 27 Dec 2017
(Signature and Date)

Y.R. SACHIN KUMAR HOLLA
NAME:

Confidential

ATTESTED
Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ECRON ACUNOVA LTD. Bangalore

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

PRINCIPAL INVESTIGATOR

By:_____

(Signature and Date)

NAME: DR. DNYANESH N MORKAR

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EXHIBIT A: PROTOCOL

As annexure 1

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EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : **Dr. Dyanesh N Morkar**

Site Address : **KLES DR Prabhakar Kore Hospital and MRC, Nehru Nagar, belagavi-590010**

PAYMENT SCHEDULE

Payment Schedule for the total study Grant of **INR 990520** for **15** patients is as follows:

Overall Per Patient Budget

Reimbursement	Amount in Indian rupees per patient	Amount in Indian rupees for total patients
Includes the following 1. Professional fees: PI and site team payment including Co- Investigator (s), Site coordinator(s), Nurse(s), as applicable	40800	612000
2. Procedural Charges	6400	96000
3. Institutional Over Head (IOH) charges 20% on Procedural Charges and Professional Charges	9440	141600
4. Patient Travel Reimbursement	3000	45000
Total Amount (INR)	59640	894600

Other payments includes

Reimbursement	Amount in Indian rupees per patient	Amount in Indian rupees for total patients
Screen Failure	8240	24720 (Considering 3 subjects)
Study Start-up		40000
Archival Charges		30000
Digital Hygrothermometer		1200

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Investigator Site Budget estimate - TLE 400mg							
	Screening	Baseline	Week 4	Week 12	Week 24	Week 28	
Investigator fees	4000	5000	4000	4000	4000	5000	**26000**
Study Coordinator	1500	2000	1500	1500	1500	2000	**10000**
Phlebotomist	300	500	500	500	500	500	**2800**
Hospitalization for PK sampling	0	4000	0	0	0	0	**4000**
PK sampling-Professional fees	0	1000	0	0	0	0	**1000**
PK sampling-Phlebotomist	0	1000	0	0	0	0	**1000**
12 lead-ECG	300	0	0	0	0	300	**600**
PT and INR	250	250	250	250	250	250	**1500**
UPT	100	100	0	0	0	100	**300**
Total (Visit Wise)	**6,450**	**13,850**	**6,250**	**6,250**	**6,250**	**8,150**	**47,200**
IOH 20%							**20%**
IOH							**9440**
Patient Travel Reimbursement	500	500	500	500	500	500	**3000**
Grand Total/subject							**59,640**
No of subjects planned**	**15**	**15**	**15**	**15**	**15**	**15**	
Estimated Amount/ Total subjects	**96,750**	**2,07,750**	**93,750**	**93,750**	**93,750**	**1,22,250**	**7,08,000**
IOH 20%							**1,41,600**
Patient Travel Reimbursement	**7,500**	**7,500**	**7,500**	**7,500**	**7,500**	**7,500**	**45,000**
Grand Total/ Total subject/site							**8,94,600**

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Summary of Budget/Payments:

Table A:

Details	Per Patient Grant	For 15 patients
Procedural Charges	6400	96000
Professional Charges	40800	612000
IOH 20% on Procedural Charges and Professional Charges	9440	141600
Patient Travel Reimbursement	3000	45000
Grand Total	**59640**	**894600**

Table B: Screening Failure

Details	Per Screen Failure	For 3 patients
Screening	6450	19350
IOH 20% on Screening	1290	3870
Patient Travel Reimbursement	500	1500
Total	8240	24720

Table C:

Details	Charges
Study start up	**40000**
Archival Charges	**30000**
Digital hygrothermometer	**1200**

Details	Grand Total	Total # of subjects	Per Patient grant
	990520	**15**	**66035**

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The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

Payment Schedule for the advance payment is as follows:

1. Non- Refundable Study startup cost INR. 40,000/- will be paid after SIV
2. CRO will pay only INR. 8240/- amount for screen failure patients as per Exhibit A of this agreement with the maximum ratio of 5:1 i.e. maximum one screen failure per five randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).
3. The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion.
4. A Non- refundable amount of INR 30,000/- will be paid to the site as Archival fees after Site Close-out Visit. The duration of archival will be for 3 years after site close out visit. After completion of 3 years of archival, the PI is responsible to consult Mylan for further instructions to transfer the study documents from site to the Archival facility as per Mylan confirmation. Ecron will be responsible for arranging the pickup and ensure the delivery of these documents from Site to the Archival facility.
5. Discontinued or Early Termination Patients: Discontinued or early termination patient will be reimbursed based on the number of confirmed completed visits and the eCRF completion.
6. Reimbursement of Clinical Trial Subjects: Clinical Trial Subjects are reimbursed for their travelling to site either according to pertinent receipts or by paying them an expense flat charge of INR 500/- (in words: Five hundred only)

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within thirty (30) days after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

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In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have forty five (45) days after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices:

Invoices shall include the heading "study code (EA-CT-17-004) or Protocol ID (MYL -TLE 400 -4001)". They shall be sent from site to CRO on a regular basis and shall be addressed to
Send invoices to:

Contact Person: <<Name of the Study Project Manager>>
Address : Ecron Acunova Limited, Mobius Towers, SJR i-Park, EPIP, Whitefield, Bangalore - 560 066. India .

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.
Payments under this Agreement shall be made upon receipt of an appropriate invoice.

Final Payment

The final payment will be made after the close-out visit by the CRO, CRA, after all CRFs for all subjects have been received and accepted by a CRO project leader, and all data queries for Institution have been resolved satisfactorily.

Budget notes, payment schedule, conditions of payment and payment directions

1. All amounts above are in Indian Rupee (INR).
2. Lab Investigations: The study requires lab examination at screening, baseline, week 4, week 12, week 24 and end of study. The local lab investigation charges if any will be reimbursed on actual, as per invoices.
3. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.
4. Please note that approx. 50 % of the total amount of the last invoice will be considered as retention amount and will be paid at the end of study/ study close out; once all the study related procedure and documentation would be over.
5. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.

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6. Payee represents that the services it provides under this Agreement are taxable service under the laws governing in India, and that it is required to charge taxes as per the applicable laws, as may be amended from time to time depending on the change in tax regulations.
7. In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.
8. Reimbursement of Meetings: The Sponsor shall reimburse the Investigator upon prior written approval for reasonable expenses on travelling and lodging which occurred through his/her participation in meetings on request of the Sponsor.

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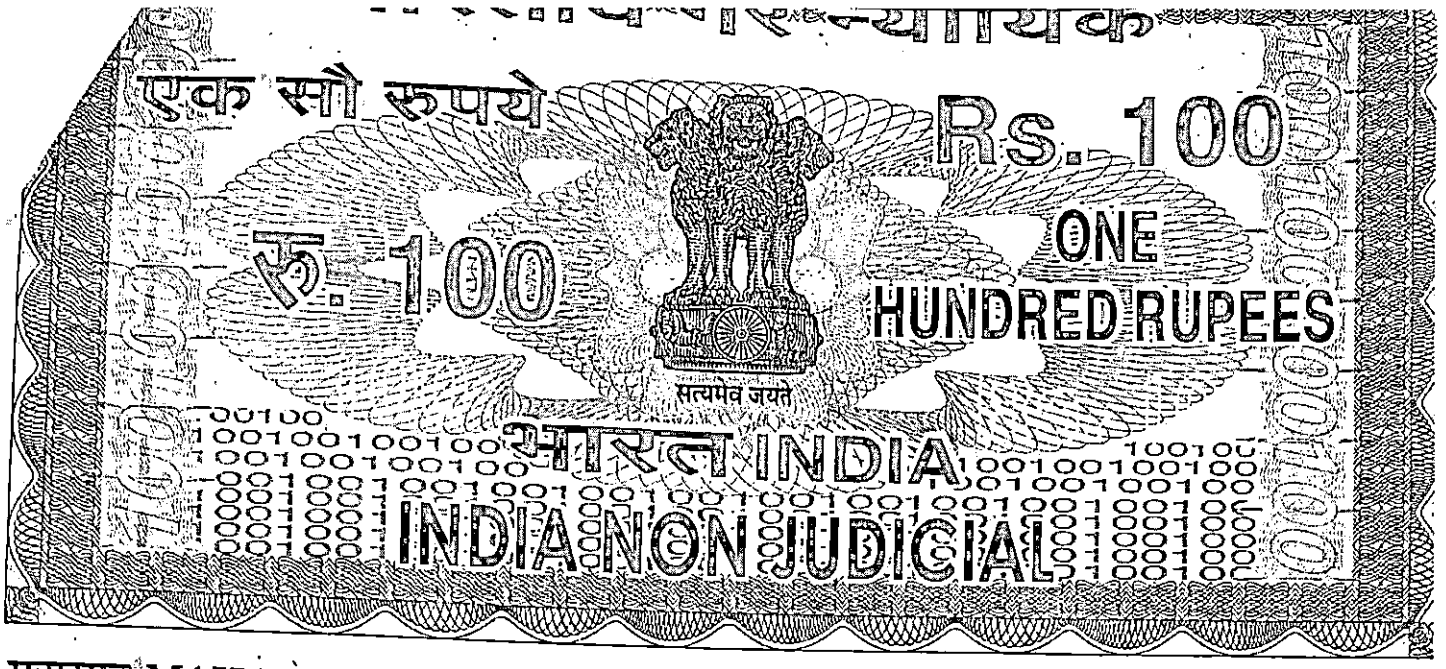
Prof Dr V.A. GHIVARE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI



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जिल्हा कोषागार कार्यालय,
ठाणे
- 2 NOV 2017
मुद्रांक प्रमुख लिपीक / लिपीक

2/11/2017

CLINICAL TRIAL SERVICES AGREEMENT

This Agreement is made and entered into this 13/Nov/2017 by and between:

Principal Investigator,
Dr. Siddalingeshwar Ishwarappa Neeli
KLE's Dr. Prabhakar Kore Hospital & MRC,
Nehru Nagar,Belagavi-590010

And

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
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INSTITUTION: The CRO has approached the INSTITUTION on behalf of the SPONSOR, as the SPONSOR desires the INSTITUTION to perform the study in regards to the said Investigational Product in accordance with the following standards:

(a) The current World Medical Association Declaration of Helsinki titled "Ethical Principles for Medical Research involving Human Patients";

(b) The current ICH Harmonized Quadripartite Guideline for Good clinical Practice

(c) The current Indian Ministry of health and Family Welfare Guidelines for good clinical practice titled, "Good Clinical Practices for Clinical Research in India";

(d) The current Indian Council of Medical Research on Human Patients;

(e) The written requirements of all reviewing institutional ethics committees;

(f) The Principal Investigator requirements;

(g) All policies and procedures of the INSTITUTION;

(h) All current and applicable permission, licenses, approvals, federal wide assurance and certifications and (1) all current and applicable laws and regulations (such as standards set forth in Sections 2(a) – (i) collectively referred to hereafter as the Standards) and;

(i) In accordance with the final protocol, patient information sheet, informed consent documents and case report forms for the above-referenced clinical study (collectively, the Clinical Trial Protocol, a current version of which is attached hereto, which attachment shall be replaced in the final version and all amended versions, if any).It is understood and agreed that, in the event of a conflict among any of the standards, the most stringent standard shall apply.

2. PERFORMANCE:

a) Protocol and Standards: Principal investigator who will supervise and direct the work of the INSTITUTION and the Dean of the INSTITUTION, hereby confirm that they have read and understood the Clinical Trial Protocol for the Study to be conducted in 399 patients and further confirm that their research team is properly trained concerning the clinical trial Protocol and Standards. All amendments have also been read and understood. The Principal Investigator and the INSTITUTION agree to the final Clinical Trial Protocol and to perform the study in strict accordance with this Agreement.

b) Subcontracting: Services of Principal Investigator: The INSTITUTION shall not subcontract the performance of any or all of its obligations under this Agreement to any third party (including to any affiliate). The services of the Principal Investigator are considered essential for the performance of this Agreement. If for any reason the Principal Investigator becomes unavailable or otherwise unable to supervise and direct the activities under this Agreement, INSTITUTION shall promptly notify the CRO/SPONSOR. If a mutually acceptable successor is not promptly identified, this Agreement may be terminated by the CRO.

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this Agreement, that subject enrollment will be completed approximately in four months from the date of Site Initiation Visit, and that the Clinical Study will be completed as per the study schedule, unless otherwise terminated in accordance with Section 7.

Recruitment: The Principal Investigator understands and agrees that the CRO/SPONSOR requires at least 339 evaluable patients at the conclusion of the Study from approximately 9-12 sites, hence it will be necessary for the INSTITUTION to enroll 35-40 patients (considering a drop-out rate of 15%) to achieve the targeted number of patients who satisfy all enrollment criteria specified in the Clinical Trial Protocol, within a period of 2-3 months approximately after the SPONSOR authorizes commencement of the study.

Confidentiality:

i. Definition: During the term of this agreement (period of five years thereafter), the INSTITUTION and Principal Investigator may have access to information, know-how, knowledge and data in oral, written, electronic, graphic or other tangible form, confidential or proprietary to SPONSOR or to SPONSOR's other collaborators (other than the INSTITUTION) and is, therefore of a confidential nature (confidential information). Confidential information shall include the Clinical

Trial Protocol, SPONSOR's Investigator's Brochure concerning the Investigational Product data, all Study Data, all documents maintained in the Clinical Trial Record Binder (site documentation), any other data emerging out of the protocol, any other information supplied by SPONSOR/CRO during the course of the study and clinical development plan, except the information already existing in the public domain, and all results and reports obtained, collected, conceived, processed and developed pursuant to this Agreement.

ii. Use: The INSTITUTION shall hold all confidential information and shall disclose confidential information only to its Principal Investigator, Co-Investigators, hospital staff and employees who have a need to know such confidential information for the purpose of this agreement and who agree in writing to keep such confidential information, confidential under terms substantially similar to those set forth herein. The INSTITUTION shall use confidential information for the sole purpose of providing services under this Agreement and shall not use confidential information for the INSTITUTION's own benefit at any time. No right or license under any patent application, trade secret or other proprietary right now or hereafter owned or controlled by the SPONSOR or other collaborators is granted to the INSTITUTION from the provision of confidential information hereunder. The INSTITUTION shall comply with the Study Data Confidentiality conditions.

iii. Provision to CRO/SPONSOR: The INSTITUTION agrees that, at any time upon CRO/SPONSOR's request, it shall promptly provide to the CRO/SPONSOR respectively, copies of all Confidential Information under this Agreement. The INSTITUTION further agrees that upon any termination or expiration of this Agreement, it shall at CRO/SPONSOR's election, return to the CRO/SPONSOR or destroy all copies of all Confidential Information; however, that the INSTITUTION may retain two (2) archival copies, with obligation to maintain the confidentiality of such confidential information.

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Work Product:

i. Definition: The Parties agree that all work performed by the INSTITUTION hereunder including, without limitation, all study data, results, reports, inventions, discoveries, new uses or know-how obtained, collected, conceived, processed, developed, improved or reduced to practice by Principal Investigator or the INSTITUTION's other hospital staff or employees pursuant to this Agreement (collectively, work product) shall be the property of the SPONSOR.

ii. Disclosure, Assignment and Provision to CRO/SPONSOR: The parties agree that the INSTITUTION shall promptly disclose to the CRO/SPONSOR any and all work related to the product comprising inventions, discoveries, new uses or know-how obtained. As per the agreement, the CRO/SPONSOR can review and obtain copies of all work related to the product including and without limitation, all study data, in an agreed–upon format and with a complete glossary of terms used for such data.

iii. Materials: The study medication, blood samples from patients under the study and all other tangible material provided to or obtained by the INSTITUTION under this Agreement (Collectively the Materials) shall be the property of the SPONSOR and/or SPONSOR's other collaborators (other than the INSTITUTION). The INSTITUTION shall use the Materials forthe sole purpose of providing services under this agreement and shall not use the materials for its own benefit at any time. No right or license, any patent, patent application, trade secret or other proprietary right now or hereafter owned or controlled by SPONSOR or SPONSOR's other collaborators is granted to the INSTITUTION from the provision of materials hereunder. Upon any remaining Investigational Product and other Materials received or obtained hereunder in accordance with the Protocol, standards and the directions of CRO/SPONSOR.

g) Human Patients: The INSTITUTION shall be responsible for safeguarding the rights and welfare of patients in the study. The INSTITUTION shall ensure (i) the rights and welfare of each such patient are protected, (ii) informed consent of each such patient is freely and knowledgeably given: (A) to participate in the study and (B) for the collection by, processing by and disclosure to and between the CRO representatives of SPONSOR, Principal Investigators and Researcher, Study Monitors, Study Laboratory Personnel, Study Data Analysts, members of the Independent Ethics Committees and representatives of governmental and inter-governmental agencies in India; (iii) the balance between risk and potential benefit from participating in the study has been assessed and deemed acceptable; and (iv) the SPONSOR/CRO has made appropriate arrangements to eliminate, mitigate and/or compensate for the consequences to such patients and their families in case of any death, injury or illness which has causal relationship with the Erectile Dysfunction and Premature Ejaculation treatment for which the SPONSOR/CRO has agreed to assume liability. Such arrangements shall include medical treatment and financial relief as per the Policy provided by Sponsor.

Ethical Approval: The INSTITUTION shall petition for written certification of ethical approval of the Study from its Institutional Ethics Committee. The INSTITUTION shall keep the CRO/SPONSOR fully advised of the progress of such submission and shall

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upon request, provide the CRO/SPONSOR with all correspondence relating to such submission. The INSTITUTION shall obtain such certification prior to screening any patients for the Study, annually after obtaining such certification, and prior to implementing any changes to the Clinical Trial Protocol. Upon receipt of such certification, the INSTITUTION shall promptly provide a copy to the CRO/SPONSOR.

h) Case Report Form Handling: The Principal Investigator shall be responsible for providing correct Case Report Forms ("CRF") according to the following:

i. The main objective of the CRF is to obtain those data required by the Protocol in a complete, accurate, legible and timely fashion. The data in the CRF must be consistent with the relevant source documents, and they must be suitable for submission to authorities.

ii. The data recorded in the course of the Study shall be documented in the CRFs and, as necessary, on the SAE report. They will then be forwarded to CRO/SPONSOR for data management and biometric analysis.

iii. The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to the CRO/SPONSOR.

iv. Wherever possible, all data obtained in the course of the Study must be recorded in the original patient files. Data to be recorded directly on the CRFs and considered as source data will be identified as such. All data in the CRFs must correspond exactly with data recorded in the source documents.

v. If CRFs are not complete the Principal Investigator shall be obliged to complete them on request of CRO/SPONSOR.

j) Drug Safety: The recording of Adverse Events (AEs) is an important aspect of study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of CRO/SPONSOR Medical Monitors concerning any AEs. According to the Protocol, the Principal Investigator will assess at each visit whether any Adverse Event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the patient or observed by the Principal Investigator/Study personnel during the entire study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship. The Principal Investigator must immediately report all Serious Adverse Events (as defined in the Protocol), which occur during the course of the Study and up to the date of the patient's last visit, to the addressee given below. The SAE Report Form will be used for documentation and reporting. Initial and follow up SAE reports are to be sent to **CRO** for onward transmission to SPONSOR:

Name: Dr. Neeta Nargundkar
Telephone Numbers: (022) 41006794
Cell Number: +91-9029025200
E-mail: drneeta@biospherecro.com

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If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the study medication CRO shall be informed immediately by telephone and followed immediately by mail. CRO will be responsible to notify on-time the health authorities in India.

k) Source Data: The Principal Investigator shall be responsible for providing the Source Data according to the following regulations. Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically, but not limited to they comprise:

i. Signed Informed Consent Form
ii. Patient hospital file and individual clinical notes
iii. Laboratory Reports
iv. Pharmacy Records
v. Study specific source documents
vi. Appropriate sections of the CRF, where data are recorded directly onto specific forms
vii. Other reports and records of any procedure performed in accordance with the Protocol

l) The Principal Investigator shall safely maintain the original study documentation together with all source data for the maximum period of time permitted by the hospital, research institute or practice in question, but not less than 5 years after the clinical part of the trial has been completed. If archiving can no longer be maintained at site, the Principal Investigator will notify CRO/SPONSOR.

m) Investigator Study File and Archiving: The INVESTIGATOR shall prepare and maintain complete and accurate study documentation in compliance with ICH-GCP standards and local regulations. Therefore, an investigator study file shall be prepared which contains all relevant documents necessary for the conduct of the study:

i. Signed Protocol and Amendments
ii. Investigator's Brochure and Updates
iii. EC Composition, approval(s)/opinion correspondence/reporting
iv. Notifications of regulatory authorities
v. CVs and signature sheet for key study personnel (e.g. Investigators, Study Nurses)
vi. Signed study agreements including financial agreement.
vii. Trial Initiation Report
viii. Approved and signed Informed Consent Forms
ix. Patient Insurance Certificate
x. CRFs (Investigator's copy)
xi. Data Clarification Forms (copies)
xii. SAE documentation and related correspondence/reporting
xiii. Shipping/accountability/destruction records for investigational product
xiv. Certificate of Analysis
xv. Instructions for handling of investigational product
xvi. Laboratory accreditation/certification and up-to-date reference ranges of normal values q Screening, enrollment and monitoring logs and subject identification code list

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xvii. Appointment diaries
xviii. Study related correspondence with CRO/SPONSOR

n) Documentation and Material (Supplies): All supplies provided to the Principal Investigator for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

n) The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of unused material for the Study, supplied by the CRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to the CRO/SPONSOR. In the latter case, *the identification and quantity of each unit of study medication and the person in charge* must be documented.

o) Monitoring, Quality Assurance and Inspection by Authorities: The Study will be monitored by the CRO. Its representatives (alone or together with representatives from SPONSOR) will be allowed access to all information resulting from this Study and SPONSOR will have an unrestricted right to use such information. CRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring and remote monitoring throughout the Study. The tasks of the monitor comprise the following:

i. to ensure Protocol adherence
ii. to verify the data in the CRFs against source documents (SDV)
iii. to check progress of the study and to motivate, if necessary
iv. to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
v. to check all data for possible SAEs and AEs
vi. to review signed informed consent forms for signatures and date of consent
vii. to ensure accurate record of drug accountability
viii. to ensure adequate storage of study supplies
ix. to collect completed CRFs
x. to discuss and help resolve any problems

p) Source Data Verification (SDV) shall be performed on 100% of key data such as informed consent, demographics, inclusion/exclusion criteria, parameters for the evaluation of the main endpoints, safety evaluation and drug accountability.

q) The visits shall involve the Principal Investigator or his appointed representative(s) and any other staff, as required. The Principal Investigator shall ensure that sufficient time is allowed for monitoring visits. Follow-up correspondence between the Site and the CRO relating to apparent inconsistencies or clarification of CRF entries will be kept on file at both CRO and the Site.

r) Study Protocol, Patient Information Leaflet/Consent Forms, CRF and Trial Report as well as each step of data recording, monitoring and processing shall be subject to the independent Quality Assurance at CRO.

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[illegible] according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of the CRO/SPONSOR.

t) For monitoring visits and in case of audits and inspections by authorities, the Principal Investigator must provide direct access to the complete study records including CRFs, original source data, study documentation, and, if necessary, any additional background data. Furthermore, access to Study related facilities must be ensured.

u) Confidentiality of Patient Records: The INSTITUTION and the Principal Investigator must assure that Study patients' anonymity will be maintained, and that their identities will be protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On CRFs or other documents removed from the INSTITUTION, patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator is obliged to maintain a subject identification code list showing the patients' full name and date of birth together with the corresponding patient identification number to allow revealing identity of any subject.

v) The Principal Investigator agrees that representatives of CRO/SPONSOR, of the responsible IEC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and CRO guarantee for their representatives that patient data will be treated confidentially. Monitors and Auditors are further bound to secrecy.

4. AMENDMENTS: The CRO, on behalf of the SPONSOR, may from time to time, make changes to the Protocol. Changes in the Protocol must take the form of written amendments and shall be approved by all signatories of the final version of the Protocol. Any amendments to the Protocol which affect the patient (e.g. changes in procedures/assessments or matters relating to patient safety) require approval of the relevant ethics committee as well as further informed consent from each concerned patient prior to implementation. The Principal Investigator shall obtain such approval. Changes of purely administrative nature shall be notified to the committee by the Principal Investigator, but do not require formal approval.

5. INSPECTIONS:

a) By Representatives of CRO/SPONSOR: The INSTITUTION agrees that CRO/SPONSOR's representatives and clinical monitors for the Study will have free access to the INSTITUTION's facilities and all documents pertaining to the Study during normal business hours, after provision of prior written notice, as is necessary to ensure that the Study is conducted in accordance with this Agreement. In the event any such representative or monitor observes non-compliance with this Agreement, incomplete, illegible or inaccurate recording of Study data, or other matters of concern relating to the Study, the INSTITUTION shall, in cooperation with such representative or monitor, promptly remedy such non-compliance, Study data recording problems or matters of concern and shall promptly notify such representative or monitor of such remedial actions taken.

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...governmental representatives: The INSTITUTION agrees that representatives of the government will have access to its facilities and such documents pertaining to the study as may be legally requested by such representatives. The INSTITUTION shall not disclose individually- identifiable personal information, individually-identifiable health care information or other Confidential Information to such governmental representatives except as required by law, and if the INSTITUTION discloses such individually-identifiable information or other Confidential Information to such governmental representatives, the INSTITUTION shall seek an appropriate, written agreement of confidentiality from such governmental representatives prior to making such disclosure. The INSTITUTION shall promptly provide copies to the CRO/SPONSOR of any notices, correspondence and other documentation received or prepared by or on behalf of the INSTITUTION in connection with any governmental inspection, action; inquiry or correspondence relating to or that may affect the INSTITUTION's activities under the Study. The INSTITUTION shall take all actions necessary to remedy any non-compliance cited by governmental authorities and shall promptly notify CRO/SPONSOR of such remedial actions taken.

6. **WARRANTIES AND DISCLAIMER OF WARRANTIES:** INSTITUTION warrants that all services provided under this Agreement will be provided in a professional and workmanlike manner, in compliance with the Standards and the terms of this Agreement.

7. **AGREEMENT TERM AND TERMINATION:**

a) This Agreement is effective as of beginning of the study, and shall continue until 5 (five) years after completion of study, unless terminated sooner in accordance with this Article 7 or unless extended for a defined period by a signed written amendment in accordance with Article 14.

b) The Study and this Agreement may be terminated by written notice from the SPONSOR/CRO to the INSTITUTION for any of the following reasons:

i. Notification to CRO/SPONSOR from applicable regulatory authorities to terminate this Study.
ii. Determination by CRO/SPONSOR that the INSTITUTION is not performing the Study as required in the Agreement and/or is not meeting the agreed upon patient enrollment requirements set forth in Section 7(c) herein.
iii. Failure of the Principal Investigator and/or the INSTITUTION to provide access to the SPONSOR monitors or SPONSOR representatives to the INSTITUTION's facilities and all original medical records and Study-related documents necessary to verify entries on Study Case Report Forms and the INSTITUTION's compliance with this Agreement.
iv. Failure of the Principal Investigator or associated staff or any other person engaged in the Study (excluding patients) to be available, upon reasonable notice and by prior mutually convenient time appointment by CRO/SPONSOR, to meet with the CRO/SPONSOR monitors or CRO/SPONSOR representatives during the course of the Study as necessary to discuss information relevant to the Study.
v. Unauthorized replacement of Principal Investigator, in accordance with Section 7(b) herein.
vi. Determination by SPONSOR that business or scientific considerations require termination.

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vii. Case Report Forms provided to the Principal Investigator by the CRO/SPONSOR for use in the Study are not completely, accurately and/or legibly completed and/or forwarded to the CRO/SPONSOR's designated representative, as appropriate, within one (1) week of each patient's visit date.

c) The INSTITUTION may terminate this Agreement by written notice from the INSTITUTION to the CRO/SPONSOR for any of following reasons:

i. SPONSOR does not comply with the Clinical Trial Protocol provisions related to supply of Investigational Product for the Study, or the CRO/SPONSOR does not supply other agreed-upon study related material.
ii. The Principal Investigator reasonably suspects an adverse reaction/adverse event related to the Study procedure and of serious nature, after informing the Institutional Ethics Committees and the CRO/SPONSOR.

d) In case of any termination or expiration of this Agreement:

i. Responsibility for treatment of enrolled patients will be as specified in the Standards;
ii. The INSTITUTION shall cooperate with the SPONSOR/CRO for an orderly wind-down of activities, with due regard for patient safety and welfare;
iii. The INSTITUTION shall return or destroy all Confidential Information to CRO/SPONSOR, at the CRO/SPONSOR's election, in accordance with Section 7(d)(iii) herein;
iv. The INSTITUTION shall promptly provide all Agreement deliverables due to the CRO/SPONSOR and, if requested by the CRO/SPONSOR, provide copies of all Work Product (including without limitation all Trial Data) to CRO/SPONSOR, in accordance with Section 7(d) (ii) herein;
v. The INSTITUTION shall return and/or dispose off all remaining Investigational Product or other Materials received or obtained hereunder, in accordance with the Protocol, Standards and the directions of CRO/SPONSOR, in accordance with Section 7(d) herein;
vi. The INSTITUTION shall, within thirty (30) days after such termination or expiration, provide a final invoice to the CRO; and
vii. The INSTITUTION shall, notwithstanding such termination or expiration, remain responsible for compliance with all Standards.

e) The provisions of Articles 5, 6, 7, 8, 9, 10, 12 and 13 herein shall survive any termination or expiration of this Agreement, as shall such other provisions as, by their context, are intended to survive such termination or expiration.

Effect of Termination

The Institution shall comply all the standard procedures required for study close out

8. RECORDS: The INSTITUTION shall maintain in the English language (a) all Work Product; and (b) complete, accurate and legible scientific and clinical documents, books and records pertaining to all activities performed and all Materials provided or obtained under this Agreement. The other Study materials will be archived at the INSTITUTION for the period set forth in the Clinical Trial Protocol and originals given to the CRO for

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a) Both the INSTITUTION and CRO shall treat matters of authorship in a proper, collaborative spirit, giving credit where it is due and proceeding in a manner that fosters cooperation and communication.

b) It is hereby expressly made clear that all Intellectual Property Rights in the final test report as well as in the material generated during the process of Clinical trial will reside with the SPONSOR. CRO.

10. FINANCE:

a) The expenses of the Study, as set forth in the total projected budget, shall be paid by the CRO and are estimated not to exceed the amount mentioned in the total projected budget, in case it exceeds it will be mutually agreed upon on reasonable grounds and documented appropriately. The CRO's payment to INSTITUTION is contingent upon the CRO receiving payment from the SPONSOR. Funds shall be paid by the CRO to the INSTITUTION for the satisfactory and timely performance under this Agreement, as per the payment details, terms and conditions laid out in

b) ***Annexure A.***

All payments will be based on actual patient visits for every 3 months.

Method of payment

CRO, on behalf of the Sponsor shall pay the relevant cost and fee as set out in Annexure A to the Institution and Institution will pay Principal Investigator.

Details of Payee are:

Trial Payment

Payee Name: CMS Clinical Research Pvt. Ltd.
PAN Number: AAFCC8457M

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country and CRO will deduct the tax at the time of making payments unless a valid Certificate) from tax authority is made available.

c) An insurance policy, as relevant, for the participating patients covering any injury or illness suffered as a direct result of their participation in this Clinical Study shall be taken out by the SPONSOR/CRO. All participating patients will be informed by the *Principal Investigator about the existence of the insurance policy and the extent of the* coverage.

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11. PUBLICITY, PRODUCT PROMOTING ACTIVITY AND COMMUNICATION GUIDELINES:

a) The SPONSOR shall not identify or use the names, trademarks, trade names or symbols of the institution, Principal Investigator or his research team under the study without the prior written permission of the Principal Investigator and head of the institution for claims, publicity or any product promoting activity. because the SPONSOR is a publicly funded organization that must maintain a certain level of transparency about its collaborations, SPONSOR may disclose the identity of the INSTITUTION, publicly available information about the INSTITUTION and the broad purpose of the collaboration under this Agreement to third parties such as a Court of Law, regulatory agencies, governmental or legal agencies, other collaborators, other investigators involved in the project and the organization (profit or non-profit) funding the development of theInvestigational Product. Also such details can be shared in scientific forums and with other medical professionals, if questioned.

b) The INSTITUTION shall not identify or use the names, trademarks, trade names or symbols of the SPONSOR, the SPONSOR's employees or affiliates, SPONSOR, SPONSOR's employees, donors or affiliates or any other author of the primary collaborative publication described in Section 11(b) herein for publicity or product promoting activity.

c) Prior to the beginning of the Study, the CRO/SPONSOR shall develop external communication guidelines for use by the INSTITUTION. The INSTITUTION agrees to comply with such guidelines. The INSTITUTION shall not issue any press release concerning the Study or this Agreement without the prior, express written approval of SPONSOR.

12. LIMITATION OF LIABILITY: The parties expressly agree that there shall be no limitation on either Party's liability for any claims, damages, losses or liabilities arising out of *or related to this Agreement or the services performed hereunder.* IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OF USE OF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE PATIENT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK. Any disputes that arise during the study between SPONSOR/CRO and Principal Investigator will be under the jurisdiction of Mumbai courts.

i. APPLICABLE LAW AND ARBITRATION: This Agreement is entered into and will be deemed for all purposes to have been made in Mumbai, India and shall be governed and construed in accordance with the laws of India applicable to contracts and agreements. The parties shall share equally the costs of the Arbitration unless *determined otherwise.*

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AMENDMENTS: This Agreement may only be amended by and to such degree as specified by the mutual written consent of the parties hereto.

14. **ENTIRE AGREEMENT:** This Agreement, contains the entire understanding of the parties with respect to the subject matter hereof and except as expressly set forth herein, all express or implied agreements, representations and understandings, either oral or written, made prior to this Agreement are hereby expressly superseded by this Agreement. In the event there is a conflict between the Clinical Trial Protocol and the terms in the body of this Agreement, the terms in the body of this Agreement will govern with respect to commercial and contract terms, but such Protocol will govern with respect to the conduct of the Study and with respect to serving the welfare of patients of the Study. This Agreement may only be amended by a written instrument executed by the parties hereto, and CRO must approve any such amendment in writing prior to such amendment becoming effective.

16. **SEVERABILITY:** The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

17. **ASSIGNMENT:** The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of the CRO. The CRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates.

18. **WAIVER:** No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this Agreement.

19. **NOTICE:** *Any notice required or permitted hereunder shall be in writing and shall be* deemed given as of the date it is (A) delivered by hand or (B) received by registered or certified mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

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WHEREOF, the parties hereto have executed this Agreement in quadripartite by proper persons thereunto duly authorized.

If to Principal Investigator:	If to INSTITUTION:
Dr. Siddalingeshwar I. Neeli M.S.,DNB (GEN.SURG.),M.Ch.,DNB (URO) Consultant Urologist KLES Dr. Prabhakar Kore Hospital & MRC Belgaum-10 Dr. Siddalingeshwar Ishwarappa Neeli KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar,Belagavi-590010	Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI. Dr. M. V. Jali Medical Director and Chief Executive KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010
If to SMO: CMS Clinical Research Pvt. Ltd. Ms. Nidhi Singh Head- Clinical Operation CMS Clinical Research Pvt. Ltd. Newbridge Business Centre, Inox Tower-B, Plot No. 17, Sector-16A, Film city, Noida, India	**If to CRO:** BIOSPHERE CLINICAL RESEARCH PVT. LTD. MUMBAI 13 NOV 2021 Dr. Neeta Nargundkar Managing Director, Biosphere Clinical Research Pvt. Ltd.,20/21, Gr. Floor, Lake City Mall, Kapurbawadi Naka, Thane (W) - 400 607, Mumbai, Maharashtra.

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Annexure A

Name of the Site: KLE's Dr. Prabhakar Kore Hospital & MRC

Provisional Investigator Site Payment-Per Patient cost is as follows:

Visit Number	Payments INR
Visit 1- Screening visit/Baseline	2830
Visit 2- Randomization visit	2000
Visit 3- Follow-up visit	1800
Visit 4- Follow-up visit	1800
Visit 5- Follow-up/End of Study visit	2830
Total	**11200 INR**

Note 1: The above payments are inclusive of Investigator Fees, Sub-Investigator Fees, Institutional Overheads and Administrative Charges, applicable for this study.

Note 2: Lab Charges excluding Penile Doppler for Visit 1 and Visit 5 will be INR 2210/- and INR 730/- respectively. Penile Doppler charges of INR 1300/- per test will be paid at actual.

Note 3: Subject Travel Reimbursement charge will be INR 500/- per visit.

Note 4: Clinical Research Site Coordinator Fees 10,000/- Per Month will be paid from Site Initiation Visit to Site Close-out Visit.

Note 5: The above payments are applicable only for randomized completed subjects.

Note 6: For Screen Failure subject charges will be paid INR 2830/- per subject. Lab Charges of INR 2210/-and Penile Doppler charges of INR 1300/- as applicable; this will be paid only to 10% of the total randomized completed subjects at the site.

Note 7: For drop-out subjects payment will be made per completed visit on pro-rated basis.

Note 8: SMO and PI will share the profit.

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NAME :_____
ADDRESS :_____
THROUGH :_____
SIGNATURE :_____
RECEIPT NO.:_____
FOR W.M.D.C. LTD.

AUTHORISED SIGNATORY

Western Maharashtra Development Corporation Ltd. 2nd Floor, Kubera Chembers, Dr. Rajendra Prasad Road, Shivajinagar, Pune 411 005. D-5/STP(V)/C.R.1014/01/08/205-208/08

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Amendment – I to the Clinical Trial Agreement

This Amendment Agreement (**"Amendment – I"**) is made as of 18th December, 2017 (**"Effective Date"**) by and between:

Lupin Limited, a company incorporated as under the Companies Act, 1956 and having its registered office at Kalpataru Inspire 3rd Floor, Off Western Express Highway, Santacruz East, Mumbai 400098 (hereinafter **"Lupin"**); and

Dr. Mallikarjun Karishetti, an Indian citizen/ resident, with his address at A14/8, Staff Quarters, J.N. Medical College Campus, Belgavi, Karnataka and having PAN: ADRPK2096A (hereinafter **"Principal Investigator"**); and

KLES Dr. Prabhakar Kore Hospital and MRC, with its address at, Nehru Nagar, Belgavi 590010, Karnataka (hereinafter **"Institution"**).

Lupin, Principal Investigator and Institution may hereinafter collectively be referred to as the **"Parties"** and individually as **"Party"**.

WHEREAS

A. Lupin and the Principal Investigator and the Institution entered into a Clinical Trial Agreement dated 14th September, 2017 (hereinafter **"Agreement"**) whereby the Principal Investigator agreed to conduct the Study under the Protocol at the Institution subject to terms and conditions contained in the Agreement.

B. The Parties are desirous of amending certain provisions of the Agreement and hence have agreed to enter into this Amendment – I.

NOW THEREFORE, THIS AMENDMENT WITNESSETH AND THE PARTIES HERETO AGREE AS FOLLOWS:

1. This Amendment – I shall be effective from 18th December, 2017 (**"Effective Date"**).

2. The Parties hereby agree that with effect from the Effective Date, Attachment – B of the Agreement shall stand deleted in its entirety and shall be replaced by Attachment – B of this Amendment – I.

3. The Parties hereby agree that with effect from the Effective Date, Attachment – D of the Agreement shall stand deleted in its entirety and shall be replaced by Attachment – D of this Amendment – I.

4. All other provisions of the Agreement shall remain binding on the Parties with full force and effect.

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5. Terms used that are not specifically defined herein shall have the same meaning ascribed to it in the Agreement. The Parties expressly agree and acknowledge that the Agreement shall stand amended to the extent specifically set out in this Amendment – I, and this Amendment – I shall form an intrinsic part of the Agreement and all the other terms and conditions of the Agreement shall continue to be valid and unchanged and binding on the Parties.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the day, month and year first hereinabove written.

Accepted and Agreed
For Lupin Ltd.

By: Dr. Dhananjay Bakhle
Its: EVP & Head – Medical Research

Accepted and Agreed
by the Principal Investigator

Name: **Dr. Mallikarjun Karishetti**

Dr. M. S. Karishetti (Khanpet),
M.D., DNB Nephrology
Chief Consultant in Nephrology,
KMC Reg No. 35503,
KLE's Dr. Prabhakar Kore Hospital and MRC
Belgaum-590010

Accepted and Agreed
For KLES Dr. Prabhakar Kore Hospital and MRC

By:
Its: Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

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LUPIN OK LEGAL

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Registrar
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Attachment – B

RESEARCH GRANT PAYMENT TERMS

B-1. General Terms. Principal Investigator("Payee") will be paid the per patient grant amount as outlined on Attachment-D (Research Grant Worksheet) per Trial Subject properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled or continuing in the Trial in violation of the Protocol.

B-2. Payment Terms. Research grant payments for each Trial Subject will be made in Indian Rupees (INR) quarterly and based on approval of invoices submitted.Invoices will be issued by Payee upon notice delivered by Lupin. Payments will be made in accordance with eCRFs submittedand monitored, and in accordance with Attachment D "Research Grant Worksheet".Monitoring will occur based on site enrollment and completion of data entry. Payments will be made in quarterly installments on a pro-rata basis. Undisputed invoices will be paid by Lupin within 60 (sixty) days of such invoice issue date.

B-3. Non-Procedural Costs. Payee will be paid for additional non-procedural costs that are pre-approved by Lupin, as set forth in Attachment D. To request payment for such costs, Payee will remit an itemized invoice to Lupin or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment D.

B-4. Final Payment. At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Lupin's review. The final payment will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Lupin Drug is returned; and all close out issues are resolved and procedures completed, including final IEC notification. All queries must be resolved within five (5) days of receipt by Payee any time during the Trial.Lupin or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any.Payee will promptly reimburse Lupin amounts overpaid within thirty (30) days of notification by Lupin or designee.

B-5. Taxes.

(1) All payments to Payee by Lupin will be subject to deduction of TDS.

(2) The Payee shall comply with all its obligations under applicable tax laws in force at the time, including all laws, rules and regulations under the Goods and Services Tax ("GST") regime ("GST Law"). In particular, the Payee shall pay its taxes and make all filings necessary under GST Law, including the GSTR-1 form, within the prescribed timelines. The Payee shall defend, indemnify and hold Lupin harmless against all losses, claims and liabilities arising out of any failure by the Payee to meet its obligations under GST Law, including any failure or error that results in denial of any tax credit under GST law to Lupin. The Payee shall fully co-operate with Lupin to respond to the relevant tax authorities' demands, and to resolve any mismatch of Lupin and the Payee's GST filings within the timelines prescribed under the GST Law.

(3) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable Authority with respect to or measured by compensation paid to Payee under this Agreement. Lupin will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

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B-6. Screen Failures. A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Trial. Screen Failures will be reimbursed, if at all, as outlined in Attachment D, based on work completed pursuant to the Protocol.

B-7. Patient travel reimbursement. Lupin, will reimburse reasonable patient travel related expenses per trial subject visit, up to the maximum amount listed in the Attachment D. Any reimbursement exceeding this limit will require prior written Lupin approval. Any payment will be based on the invoice together with supporting documentation (i.e. receipts) submitted to Lupin.

B-8. Administrative Start-up Fees. Within sixty (60) days of execution of this Agreement and receipt of a valid invoice, Lupin, will pay a non-refundable start-up payment in the amount listed in the Attachment D for the work performed to prepare for site activation and enrolment (including but not limited to, feasibility study, initial training of Protocol, briefings, advance talks, provisions of room for the monitoring, initiation of the Study at the Center, training of the future Members of the Study Team, participation in Investigator 's meetings, contract review activities, the cost for purchasing small equipment, set-up costs for equipment and all other preparation).This amount will be adjusted from final payment(s) for the Trial.

B-9. Necessary Procedures. Payee will be reimbursed for valid necessary visits and procedures. Payment for any necessary procedure due to patient safety will be reimbursed at the agreed upon unit cost in the budget, or if there is no such unit cost in the budget, at the appropriate unit cost pre-approved by Lupin in writing, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Lupin's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Lupin will be notified as soon as practicable after the fact.

B-10. Payee. The research grant payments will be made to the following payee and address:

Payee Name: **Dr Mallikarjun S. Karishetti**
Payee GST Number: **NA**
Payee PAN No.: **ADRPK2096A**
Payee Bank Account Details: **Savings**
Bank Name: **Canara Bank**
Bank Address: **KLES Hospital Branch, Nehru Nagar, Belgaum-10**
Bank Account Number: **85151010001000**
IBAN Number: **NA**
IFSC Code: **CNRB0008515**
Email address for remittance information: **DrmallikarjunK@hotmail.com**

In case of changes in the Payee's bank account details, Payee is obliged to inform Lupin in writing, but no amendment to this Agreement shall be required.

B-11. Invoices. All invoices must be issued and forwarded to the following as instructed:

Lupin Limited (Research Park),
Survey. No. 46A/47A,
Village Nande,Taluka Mulshi,
Pune – 412115, Maharashtra, India
Attn.: Dr Rajesh Kumawat

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Each invoice must contain: (1) Lupinname, (2) Protocol number, (3) Project code, (4) a summary of the reimbursement to be made in compliance with the Research Grant Worksheet, and (3) the GST Registration Number, (4) if GST reverse charge mechanism applies, the note "GST reverse charge applicable".

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation.

Any invoices submitted by the Payee more than 45 (forty five) days after the database lock will not be reimbursed.

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Attachment – D

RESEARCH GRANT WORKSHEET

Grant Worksheet

Principal Investigator: Dr. Mallikarjun Karishetti
Protocol No.: LRP/LNP1892/2016/007

Main Study	
Investigator Grant Per Patient	***Cost (INR)[1]***
Screening (All activities per protocol)	8,000
Day 1 (All activities per protocol)	10,000
Day 8 (All activities per protocol)	3,500
Day 15 (All activities per protocol)	3,500
Day 30 (All activities per protocol)	10,000
Day 60 (All activities per protocol)	10,000
Day 90 (All activities per protocol)	10,000
Day 97 (All activities per protocol)	8,000
Total per patient amount - Main Study	**63,000**
PK PD Study	
Investigator Grant Per Patient	***Cost (INR)[1]***
Screening (All activities per protocol)	8,000
Day 1 (All activities per protocol)	5,000
Day 2 (All activities per protocol)	3,000
Day 8 / EOT (All activities per protocol)	5,000
Day 9 (All activities per protocol)	2,000
Day 10 (All activities per protocol)	2,000
Day 15 / FU Visit (All activities per protocol)	2,000
Total per patient amount - PK PD Study	**27,000**
TOTAL PER PATIENT GRANT AMOUNT (Main Study & PK PD STUDY)	**90,000**

Additional Study Related Costs	***Cost (INR)[1]***
Screen Failures[2]	8,000
Patient travel reimbursement	500
12 Lead ECG (Only at Protocol scheduled time points)	400
Ultra-Sonography (USG) Neck (Only For Main study, Parathyroid Gland size assessment at protocol scheduled time points)	1,500
Hospital Per day charges (Night stay) (As per PK PD protocol schedule only)	2,000
Hemodialysis cycle (Post randomization per cycle cost, Only for patients randomized on hemodialysis arm)	2,500
Institutional Overheads[3]	20%

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Invoiced Charges[4]	*Cost (INR)*[1]
Administrative Start Up Fees	50,000
Archival Fees (For 15 Years) (includes onetime set up charge)	41,000
TOTAL Invoiced Charges	**91,000**

Notes:

[1]Total Costs are inclusive of indirect cost.

[2]Ratio: 1:1 (One (1) Screen Failure for every one (1) subject randomized into the Study. Screen Fails are

[3]Institutional Overheads would be calculated per total investigator grant payment and would be paid as a part of each quarterly payment.

[4]Invoiced Charges to be paid upon receipt of invoice from Principal Investigator, Administrative Start up fees at the time of site initiation, Archival fees before site close out

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