MEMORANDUM OF UNDERSTANDING

BETWEEN

KAHER'S SHRI B M KANKANAWADI AYURVED MAHAVIDYALAYA,

BELAGAVI, KARNATAKA.

AND

MADHAVA - AYURVEDA E YOGA, FLORIANÓPOLIS

For

Quality programs in Clinical Training, Internship, Teaching & Research in the Science of Ayurveda

ATTESTED

01

Memorandum of Understanding

This memorandum of understanding (MOU) is made on 22nd January 2020 Between KAHER's Shri B.M. Kankanawadi Ayurveda Mahavidyalaya, Post Graduate Studies & Research Centre, a Constituent Unit of KAHER (Declared as Deemed to be University U/s 3 of the UGC Act vide Government of India Notification No.F-9-19/2000-U 3 (A) Accredited 'A" Grade by NAAC, Placed in Category "A" by MHRD (GoI), Shahapur, Belagavi, Karnataka, India, hereinafter referred as KAHER'S SBMK, Belagavi, represented by Registrar, KAHER (which expression shall mean and include his successors in office and assigns) on the FIRST PART.

And

Madhava - Ayurveda e Yoga Florianópolis Brazil represented by Mrs. Adriane Mocker Novaes (Director) which expression shall mean and include his successors and assigns) SECOND PART

KAHER'S Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya, Post Graduate Studies & Research Centre (KAHER'S SBMKAM) and Madhava Ayurveda e Yoga, Florianapolis Brazil individually referred to herein as a 'party' and collectively as the 'parties'.

A: Preamble:

KAHER'S SBMKAM Belagavi is an Institute for higher learning offering educational programs in the areas of Ayurveda science. It has also established health care services in region by running Charitable hospitals of Ayurveda Sciences. There are fourteen well established departments with high-end equipment and learned faculty. The institution is imparting Undergraduate course B.A.M.S with intake strength of 100, comprising of 4 ½ year curricular study and 1 year rotator internship and Post Graduate courses in Dravyaguna, Rasashastra & Bhaishajya Kalpana, Kaumarabhritya, Agada Tantra, Swasthavritta, Kayachikitsa, Panchakarma, Rasayana & Vajikarna, Shalya Tantra, Sangyaharana & Shalakya Tantra.

KAHER'S SBMKAM is a vibrant research institute engaged in the research activity in several contemporary areas of Ayurveda. It involves in R&D in a wide range of topics in, Kayachikitsa (internal medicine), Panchakarma, Dravyaguna, Rasashastra & Bhaishajya kalpana, etc.

Madhava- Ayurveda e Yoga, Florianópolis Brazil: Mádhava _ Ayurveda and Yoga Center is a company registered as Adriane Mocker - ME with CNPJ nº 08.933.216 / 001-11 and known by the name of Mádhava - Ayurveda and Yoga. Company opened on 07/12/2007, headquartered at the Servidão Cecilia Jacinta de Jesus, 134 address, Rio Tavares District, in the city of Florianópolis / SC. Since 2007, the Mádhava Ayurveda e Yoga Center has been dedicated to the study and propagation of Ayurveda and Yoga, promoting the Ayurveda Therapist Training Course, lasting two (2) years and a workload of 400 hours. Mádhava Ayurveda and Yoga also offers health promotion activities in accordance with the original Ayurveda and Yoga precepts and in accordance with Brazilian law as per the National Policy for Integrative and Complementary Practices (PNPIC).

Both parties felt that a sustained, synergetic and effective collaboration between **KAHER'S SMBKAM** and **Madhava -Ayurveda e Yoga, Florianópolis** will enhance the strength, and add value to, the efforts of each party;

Adriane Mocker Novaes

ATTESTED

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

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The Parties therefore agree to collaborate closely to provide quality programs including clinical training, internship facility and teaching in the science of Ayurveda for mutual benefit including academic research collaboration as per the following broad objectives

B: Broad Objectives:

1. Madhava Ayurveda e Yoga, Florianapolis will depute its students who have interest in **KAHER'S SBMKAM** Belagavi for clinical placements / internship in Ayurveda.
2. **KAHER'S SBMKAM** Belagavi will provide Clinical Training & Placements to the students of Madhava Institute at its Belagavi, Karnataka (India) campus as per the schedule mutually agreed upon by both the parties from time to time.
3. Fees for Clinical Training / Placements will be mutually discussed and agreed by both parties and payment will be made to **Registrar, KAHER,** Belagavi by **Madhava Ayurveda e Yoga, Florianapolis**
4. The Clinical Training / Placements of Madhava Ayurveda e Yoga, Florianópolis students will be undertaken by KAHER'S SBMKAM Belagavi in batches of minimum of 6 - 8 students for 6 weeks.
5. The Travel arrangements of the students both International and domestic will be the responsibility of students from Madhava Ayurveda e Yoga, Florianapolis.
6. Boarding and lodging arrangements for the students during their training / placement will be made by KAHER'S SBMKAM Belagavi on share accommodation basis. Standard diet as in practice in the institute will be provided.
7. KAHER'S SBMKAM Belagavi will provide in residence experts to be part of the curriculum design and board of studies if required by Madhava Ayurveda e Yoga, Florianapolis.
8. Both the parties for the training / placement program will decide the financial terms and obligations mutually whenever needed.
9. Students travelling from Madhava Ayurveda e Yoga, Florianapolis need to travel on "Student Visas" to avoid any legal issues.

C: Mode of Operation:

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

1. This MoU shall be effective from the date it is signed by the Parties.
2. Within the broad framework of the MoU, **KAHER'S SBMKAM** and **Madhava Ayurveda e Yoga, Florianapolis** can develop joint academic training or scientific programmes, exchanges, development of facilities, etc.
3. Any financial commitment for joint activities under this MoU shall be subject to the approval by the competent authority of the respective organization.
4. The activities under this MoU shall be coordinated, monitored and recorded by a Coordination Committee constituted with members nominated by both parties; each organization will appoint a coordinator who will organize joint meetings at regular intervals at mutually agreed locations and maintain records of agreements, work plan and progress.
5. The visitors will be bound by the rules and regulations as well as code of conduct of the host institution.
6. The Internal Coordination Committee constituted by the Vice Chancellor of KAHER will formulate procedure for exchange of students, faculty and other visitors, in accordance with the rules of the host participating institutions as defined in preamble.

Adriana Locker Moraes

ATTESTED

P. G. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

03

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ATTESTED

KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

7. The mode and quantum of resource sharing will be decided based on recommendation of the Coordination Committee on a case to case basis, **subject to approval of competent authority as required.**

8. The Coordination Committee will formulate action plans at its meetings and communicate for information and necessary approvals by the concerned authorities.

D: Obligations of the Parties

1. In accordance with clause C-4 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. KAHER'S SBMKAM will train & guide students and faculties from **Madhava - Ayurveda e Yoga, Florianapolis** based on need and availability of resources as per institutional procedure.
4. The Parties shall share knowledge and facilities within the institutional rules of each Party, to:
   a) Provide access to libraries, archives, research laboratories and other facilities.
   b) Provide access to high-end instruments and equipments as mutually agreed.
   c) Share knowledge/ information and publications/magazines/literature essential for the academic pursuit.
   d) Provide logistical support for the scientists/experts involved in this MoU at both parties' locations.
   e) No financial commitment from either Organization shall be assumed unless a formal approval/acceptance to that effect has been accorded through signed documents by both the Organizations.

E: Duration and Termination

1. This MoU shall remain in force initially for a period of two years, however, it may be **renewed by mutual consent for an extended period of 2 years unless any of the parties seeks termination in writing.**
2. This MoU may be terminated prior to the expiry of the MoU as indicated above with three months notice and with the written consent of the Heads of the two organizations.
3. Termination of this **MoU** shall not terminate 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 or 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 the owning **Party** in writing. Each Party will have the exclusive ownership and rights on the independently developed intellectual property after the signing of **MoU.**

Adriane Attlocken Moraes

ATTESTED

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

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 provisions of the specific project/programmme

4. Each Party shall duly acknowledge the contribution/involvement of the other Party in a given 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 and for ***Two years*** thereafter, **Parties** undertake on their behalf and on behalf of their sub-contractors or 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.

G: GENERAL PROVISIONS

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 up on and inure to the benefit of the **Parties** hereto and their respective heirs, representatives, successors in office and assignees; and,

2. This **MoU** constitutes the entire understanding between the **Parties** relating to the subject matter hereof and supersedes and cancels any and 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 the same are made in writing by both the **Parties** or their authorized representatives 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 **KAHER'S SMBKAM – Madhava -Ayurveda e Yoga, Florianapolis** shall remain independent entities, each responsible for its own employees. Each **Party** assumes no responsibility to the other for costs, expenses, risks, and liabilities arising from the efforts of the **Party**.

H: FORCE MAJEURE

Neither **Parties** shall be held responsible for non-fulfillment of their respective obligations under this **MoU** due 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.

ATTESTED

KOTHIWALE
Registrar
Karnataka Higher Education
and Research, BELAGAVI

06

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 programmes 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 understandings 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 based 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, Karnataka, India in English language. The decision of arbitrator so reached shall be final and binding on both the parties.

K: SEAL OF THE PARTIES

In witness whereof, the **PARTIES** represented by their authorized representatives, set forth their hands on this the day, month and year first stated above, agreed and accepted this **MoU** to be signed in the presence of the following witnesses:

Sealed & signed for and on behalf of

KAHER's Shri B.M.Kankanawadi Ayurveda Mahavidyalaya, Shahapur, Belagavi.

PRINCIPAL
Shri B. M. Kankanawadi
Ayurved Mahavidyalaya
A Constituent Unit of KAHER
Shahapur, BELAGAVI-03.

Registrar,
KAHER,
Belagavi,
Karnataka, India

Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Sealed & signed for and on behalf of

Madhava Ayurveda e Yoga, Florianópolis

Adriane Mocker Novaes

[Mrs. Adriane Mocker Novaes]
Director,
Madhava Ayurveda e Yoga, Florianópolis

Adriane Mocker Novaes
Madhava - Ayurveda e Yoga
Reg: No. CNPJ08933216000111.

ATTESTED

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

07

PART II

ABOUT US KLE's College of Pharmacy (A constituent unit of KLE Academy of Higher Education and Research, Belagavi): Formally commenced its courses in 1985. Located on Poona-Bangalore highway, in a picturesque campus, the college has every possible amenity required to impart professional education. The institute offers D.Pharm, B.Pharm, M.Pharm, Pharm.D & Ph. D courses. B.Pharm course is reaccredited by NBA with effect from 31.10.2019.

Our college is one amongst the many successful ventures of K.L.E. Society, which has a reputation for pioneering in pursuit of academic excellence. Our college has achieved laurels worthy of creators and it is continuously striving for higher ground.

It has gained appreciation from the top recognizing centers in India like: Pharmacy Council of India, All India Council for Technical Education and Government of Karnataka .We have series of courses aimed at developing the best of pharma professionals.

We aim at Pharmaceutical Sciences Research that helps the communities. Proactively we work on the identification and resolving drug related problems. We work on Continuousquality improvement techniques to optimize the medication process. A host of amenities are made available for academic pursuers and researchers. Ideally located college and hostels help to foster a conducive atmosphere for studies.

PURPOSE/OBJECTIVE/GOALS

1. This MOU is to strengthen the research interest in our students and to expertise them in research activities.
2. Links to higher educational resources.
3. Promoting and facilitating Practical knowledge and to create entrepreneurship activities.
4. To carry out Projects/ Dissertations / Field Studies/ Coarse Projects in the field of formulations, bioactive synthetic and natural chemicals and bioactive studies.
5. To foster and disseminate High Quality Research and creative work which enhances Learning and contributes to the advancement of Knowledge.
6. To promote the Research which is of relevance to Industry and Commerce.which contributes to the Society.
7. To link the Chemical science with Pharmaceutical sciences and to ensure the safe, effective and affordable use of drugs.

The institutions will both together mutually decide upon terms and conditions for implementation of the above tasks.

We re-affirm our commitment to the program and our willingness to make a consistent effort to ensure that it is implemented effectively in Institutions.

The Memorandum is in force effective from this date till five years.

Principal
J. T. College, Gadag (PART I)

K.L.E. SOCIETY'S GADAG 582 101 J.T. COLLEGE

Witness: (Dr. M.B. PALKAR)

Principal, 15/2/2020
KLE's College of Pharmacy,
Hubballi (PART II)

Witness: Prof. S.V. Angadi

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

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Authorised Signature
Sri [illegible] Souhara
S[illegible] Gadag.

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

PART I

KLE Society's Jagadguru Tontadarya College affiliated to Karanatak University Dharwad was established in the year 1958 with the holiness of Shri Jagadguru Tontadarya Swamiji. The Department of Chemistry is well equipped with all the technologies. Our commitment is to provide the quality education, trying to mould the young minds to exhibit their skills&talents. To achieve thisgoal we have undertaken different projects, Industrial visits, seminars, workshops, experimental learning etc. Students are also interestingly participating and responding very enthusiastically. The major objective to sign MOU is to create research and projects interest in our students and to explore their ideas practically. Here after called as Part I.

ATTESTED

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

सत्यमेव जयते

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First Party	:	PRINCIPAL KLE COLLEGE OF PHARMACY
Second Party	:	DIRECTOR KIMS HUBBALLI
Stamp Duty Paid By	:	PRINCIPAL KLE COLLEGE OF PHARMACY
Stamp Duty Amount(Rs.)	:	50 (Fifty only)

ಕರಾರು ಪತ್ರ

ಕೆ.ಎಲ್.ಇ ಸಿಪಧ ವಿಜ್ಞಾನ ಮಹಾವಿದ್ಯಾಲಯ, ವಿದ್ಯಾನಗರ, ಹುಬ್ಬಳ್ಳಿ ಇವರ ಫಾರ್ಮ. ಡಿ. ಪಿಪಧ ವಿದ್ಯಾರ್ಥಿ ವಿದ್ಯಾರ್ಥಿಗಳಿಗೆ ತಮ್ಮ ಸಂಸ್ಥೆಯ ಆಸ್ಪತ್ರೆಯಿಂದ ಕ್ಲಿನಿಕಲ್ ಪೊಲಭ್ಯವನ್ನು 2019-20ನೇ ಶೈಕ್ಷಣಿಕ ವರ್ಷದ ಅವಧಿಯವರೆಗೆ ಕಮ್ಮ ದರದಲ್ಲಿ ಮಾಡಲಿಯು ಫಲಿತೋತ್ತರ ಮಾಜಿರಾತಿಗೆ ಒಪ್ಪಿಸುವುದು ಮತ್ತು ಈ ಕೆಳಕಂಡ ಷರತ್ತುಗಳಿಗೆ ಒಪ್ಪಿಕೊಂಡಿರುತ್ತೇವೆ.

Dr. V. G. JAMAKANDI, M.Pharm., Ph.D.
Professor & Principal
KLE's College of Pharmacy
(A constituent unit of KLE Academy of Higher Education & Research)
Vidyanagar, HUBBALLI - 580 031.

ATTESTED

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

1. ಸರ್ಕಾರದ ಆದೇಶದಂತೆ ಪ್ರತಿಯೊಂದು ಫಾರ್ಮ. ಡಿ. ಡಿಪ್ಲೊಮಾ ವಿದ್ಯಾರ್ಥಿಗಳಿಗೆ ಪ್ರತಿ ವರ್ಷಕ್ಕೆ ರೂ.೬,೦೦೦/–ರಂತೆ ಸೇವಾ ಶುಲ್ಕವನ್ನು ಭರಿಸುತ್ತೇವೆ ಹಾಗೂ ಕಾಲಕಾಲಕ್ಕೆ ಸರ್ಕಾರದ ಹಾಗೂ ಸಂಸ್ಥೆಯವರು ತಗೆದುಕೊಂಡ ತೀರ್ಮಾನದಂತೆ ಟ್ಯೂಶನ್ ಫೀ ಪರಿಷ್ಕರಣೆಗೊಂಡಲ್ಲಿ ಭರಣಮಾಡಲು ಬದ್ಧರಾಗಿರುತ್ತೇವೆ.

2. ಕ್ಲಿನಿಕಲ್ ಅವಧಿ ಮುಂಜಾನೆ 10–00 ಗಂಟೆಯಿಂದ ಮಧ್ಯಾಹ್ನ 4–00 ಗಂಟೆಯವರೆಗೆ.

3. ಪ್ರತಿಯೊಂದು ವಿದ್ಯಾರ್ಥಿಯ ಸೇವಾ ಶುಲ್ಕವನ್ನು ಪ್ರತಿ ವರ್ಷ ಶೈಕ್ಷಣಿಕ ವರ್ಷದ ಪ್ರಾರಂಭದಲ್ಲಿಯೇ ತಮ್ಮ ಸಂಸ್ಥೆಗೆ ಭರಿಸುತ್ತೇವೆ.

4. ನಮ್ಮ ವಿದ್ಯಾರ್ಥಿಗಳಿಂದ ತಮ್ಮ ಸಂಸ್ಥೆಯ ಆಸ್ಪತ್ರೆಗೆ ಯಾವುದೇ ಹಾನಿಯಾದಲ್ಲಿ ನಮ್ಮ ಸಂಸ್ಥೆಯಿಂದ ವಸೂಲಿ ಮಾಡಕೊಳ್ಳಬಹುದು.

5. ಈ ವಿಷಯ ಕುರಿತು ಯಾವುದೇ ನಿರ್ಧಾರ ಅಥವಾ ಮಾರ್ಪಾಡುಗಳನ್ನು ಮಾಡುವಲ್ಲಿ ನಿರ್ದೇಶಕರು, ಕಿಮ್ಸ್, ಹುಬ್ಬಳ್ಳಿ ಇವರ ನಿರ್ಧಾರ ಅಂತಿಮ ನಿರ್ಧಾರವಾಗಿರುತ್ತದೆ.

6. ವಿದ್ಯಾರ್ಥಿಗಳ ದುರ್ನಡತೆ ಹಾಗೂ ನಡುವಳಿಕೆ ಸರಿ ಕಾಣದಿದ್ದಲ್ಲಿ ಹೊರ ಹಾಕುವ ಹಾಗೂ ಈ ಆದೇಶವನ್ನು ರದ್ದುಪಡಿಸುವ ಅಧಿಕಾರವನ್ನು ನಿರ್ದೇಶಕರು, ಕಿಮ್ಸ್, ಹುಬ್ಬಳ್ಳಿ ಇವರು ಹೊಂದಿರುತ್ತಾರೆ.

7. ಸಂಬಂಧಪಟ್ಟ ಎಲ್ಲ ವಿಭಾಗದ ಜೊತೆಗೆ ಸಹಕರಿಸಿಕೊಂಡು ಕಾರ್ಯ ನಿರ್ವಹಿಸುತ್ತೇವೆ.

8. ಪ್ರತಿಯೊಬ್ಬ ವಿದ್ಯಾರ್ಥಿಗಳು ಕಡ್ಡಾಯವಾಗಿ ಯುನಿಫಾರ್ಮ ಹಾಗೂ ಗುರುತಿನ ಬೀಟ ಧರಿಸುತ್ತಾರೆ.

9. ಈ ಮೇಲೆ ಕಾಣಿಸಿದ ಎಲ್ಲ ಕರಾರುಗಳಿಗೆ ಒಪ್ಪಿಕೊಂಡು ಹಾಗೂ ಅದರಂತೆ ನೆಡೆದುಕೊಳ್ಳುವುದಾಗಿ ಕರಾರು ಪತ್ರವನ್ನು ರೂ.೫೦–೦೦ ಬಾಂಡ ಪೇಪರ ಮೇಲೆ ಬರೆದು ನಿರ್ದೇಶಕರು, ಕಿಮ್ಸ್, ಹುಬ್ಬಳ್ಳಿ ಇವರಿಗೆ ಸಲ್ಲಿಸುತ್ತಿದ್ದೇವೆ.

10. ಸರ್ಕಾರ / ಇಷಾಖೆ/ ಸಂಸ್ಥೆಯ ಕಾಲಕಾಲಕ್ಕೆ ಹೊರಡಿಸುವ ಆದೇಶ/ಸುತ್ತೋಲೆಗಳನ್ನು ಪಾಲಿಸಲು ಬದ್ಧರಾಗಿರುತ್ತೇವೆ.

ದಿನಾಂಕ: 23.01.2020

ಸ್ಥಳ: ಹುಬ್ಬಳ್ಳಿ

Dr. V. G. JAMAKANDI, M.Pharm., Ph.D.
Professor & Principal
KLES College of Pharmacy
(A constituent unit of KLE Academy of Higher Education & Research)
Vidyanagar, HUBBALLI – 580 031.

ATTESTED

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

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA47541499598080S
Certificate Issued Date	:	28-May-2020 11:02 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ MANJUNATHNAGAR/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08020736681634O4S
Purchased by	:	PRINCIPAL KLE COLLEGE OF PHARMACY BENGALURU
Description of Document	:	Article 12 Bond
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PRINCIPAL KLE COLLEGE OF PHARMACY BENGALURU
Second Party	:	KARNATAKA RAJYA VIJNANA PARISHAT BENGALURU
Stamp Duty Paid By	:	PRINCIPAL KLE COLLEGE OF PHARMACY BENGALURU
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

SWASTIK PRAGATHI MULTIPURPOSE SOUHARDA CO-OP LTD. BANGALORE

MEMORANDUM OF UNDERSTANDING

BETWEEN

KLE COLLEGE OF PHARMACY, BANGALORE

AND

KARNATAKA RAJYA VIJNANA PARISHAT (KRVP), BANGALORE

This memorandum of understanding is executed on this First day of June, 2020, between KLE College of Pharmacy, Bangalore (hereinafter referred to as KLE) and Karnataka Rajya Vijnana Parishath, Bangalore through their representatives for Startup Incubation Centre.

ATTESTED

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

1) A brief history of the college concerned:

In 1916, a dedicated group of teachers popularly known as "SAPTARSHIS" embarked upon a dream vision – to create a strong education base in the neglected areas of Karnataka and Maharashtra. Over the past 104 years, the KLE Society has blazed a trail and set an unparalleled example in education and service in the South. More than 210 institutions run under KLE Society. Since inception, the aim of the KLE Society has been to set unmatched standards in the quality of education, thereby creating world-class professionals who are empowered to set standards of their own, in a global arena.

Realizing the magnitude of such a task, the sponsoring Society began its efforts a decade ago under the dynamic leadership of Shri. Prabhakar Kore, Chairman, KLE Society to achieve the University status. The KLE University status has been accorded by the Ministry of Human Resource Development, on the advice of the University Grants Commission (vide their letter No. F.9-19/2000-U.3(A), dated 13-04-2006).

KLE College of Pharmacy, Bangalore is a constituent college under KLE Academy of Higher Education and Research, Belagavi. The college was established in the year 1992. It has earned a good reputation for imparting quality education, principle and deep commitment for achieving excellence. The college is reaccredited by NBA for 5 years and is recently ready for third round of reaccreditation.,

2) Karnataka Rajya Vijnana Parishat (KRVP) was founded in 1980 as an autonomous registered society it is an organization of about 79 units, 34 district committees and 653 rural school science centers's spread across the length and breadth of Karnataka. It is purely funded by science and technology department of Government of Karnataka. Bharat Ratna Prof. CNR Rao is the chief patron of KRVP. Activists and promoters of KRVP include scientists, teachers, administrators, doctors and other professionals.

FACILITIES AGREEMENT	KLE College of Pharmacy, Bangalore,
Place and date of agreement	India
Party No. 1 / (Educational Institution)	KLE Bangalore (referred to as the KLE), having its college at KLE Bengaluru Campus, Rajajinagar, India, 560010. Acting through its Principal – Dr.Raman Dang,

ATTESTED

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

Party No. 2/
(Business Incubator/Start Up Centre)

Karnataka Rajya Vijnana Parishat, Bengaluru. (referred to as the Startup Center), a society registered under the Societies Registration Act, 1860 having its office at No 24/2, 21st Main Road, BSK 2nd Stage, Bengaluru - 560010, India, acting through its Executive Committee Member / Director Mr. Kaushik P S

WHEREAS KLE will support the startup center as below.

A. To support the startup center with existing infrastructure, furniture, appliances/peripherals throughout the operating period for free without any monetary implications.
B. To support the incubation center with Wi-Fi/internet for free.
C. To cross utilize existence staff for upkeep and maintenance of the facility given to startup center.
D. Will allow the startup center to operate beyond the KLE working hours/ on weekends and holidays if needed.
E. To permit and encourage students to participate / involve in the initiatives of the incubation center.
F. To publicize startups in all its capacities in events, seminars, bulletin, etc.
G. To give priority to in-house startups.
H. To allow the startup center to conduct required training periodically.
I. Will allow the startup center to use conference halls/ auditorium for training, meeting purposes without any charge.
J. Will empower the startup center to engage with professionals/mentors to assist startups.
K. To permit startup center to partner with government, semi government, PSU AND Private ENTITIES.
L. To allow startup center to raise funds by various means to fulfill the objectives of the startup center.
M. To permit students startups promoters for participating in expo, trade/ fairs.
N. Involvement of NSS volunteers for skill based approaches in coordination with Prof. Dr.Mamatha.A, NSS Programme Officer, KLECOP, Bangalore.

WHEREAS the **Karnataka Rajya Vijnana Parishath** will assure KLE as below.

A. Partner with professionals, mentors, academicians, researchers etc.
B. Partner with organizations, government public sector undertakings, private entities, non-government organizations etc.

ATTESTED

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

C. Provide training, incubation, legal, accounting services at nil/ concessional slabs.

D. Provide insights on product design and collaterals.

E. Provide social media, web, cloud, digital, offline and online marketing services at nil/ concessional slabs.

F. Create opportunity to interact and seek insights from industry leaders.

G. Create internship opportunity across various domains/ sectors.

H. Provide networking opportunity to scale up the startups.

I. Connect with moral supporters, accelerators, collaborators, service providers, etc.

J. Support in organizing investment and connect with venture capitalists, investors etc. Also help in drafting the startup pitch.

K. Organize stakeholder meets.

L. Evaluate, handhold, monitor startups on a regular basis.

M. Submit a quarterly report to KLE on the status of the startups.

N. Identify opportunities for expansion / diversification of startups within and outside the territory of INDIA.

O. Assist in trade fairs and expos.

P. Provide requisite manpower for efficient operations of the startup center.

Q. Encourage our skilled efficient NSS Volunteers for their upgradation and also for relevant placements.

NOW IT IS AGREED BY AND AMONGST THE PARTIES HERETO AS FOLLOWS:-

Grant of Facilities required will be identified and provided in the college

A. Period of contract/ termination: THIS agreement shall remain in force as long terminated. It shall be open for either party to terminate this agreement by giving 03 months written notice, without assigning any reasons. However, any termination of the agreement shall not absolve any liability to both parties incurred under this agreement.

A1. In the event of termination of this agreement by efflux of time or by notice as herein above provided or in any other manner whatsoever, the Startup center shall hand over to the KLE, all its equipment's, machines, premises etc in good and working condition, except the normal wear and tear.

B. Prohibited business: The startup center shall not support/ carry out any activity which is not abiding the laws/ rule applicable or which is prejudicial.

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

C. Right of lien etc: The Startup center shall not have right to lien or set off on any of the assets, paper, document, instrument, property of the KLE, for the due satisfaction of any of its claim, while the KLE shall have all such rights.

D. Maintenance of record/accounts: The Startup center shall keep proper storage and updated account of all activities and all other matters and transactions concerning the commercial / administrative aspects and such accounts / records shall at reasonable times be available for the Inspection by the representatives of the KLE Bengaluru, who shall have full liberty to take copies or extracts from the same and make such queries and ask of such documents as may be expedients.

E. Jurisdiction: The agreement shall be governed by Indian laws. In the event of any dispute or difference between the KLE and the Startup center arising out of this agreement or the matter connected or incidental thereto or termination thereof, the Courts at Bengaluru alone shall have the jurisdiction in the matter.

It is also a great pride to both parties as, this would be the first Incubation center in the field of Pharmacy in Karnataka State.

For the	For the
KLE College of Pharmacy, Bangalore India	Karnataka Rajya Vijnana Parishat (KRVP) Bengaluru, India
Principal, KLECOP, Bengaluru Dr. Anand Dang	Director, KRVP Mr.Koushik
Witnesses:	
Staff Coordinator [Name & Signature] KLECOP, Bengaluru	Coordinator [Name & Signature] KRVP Start Up Centre
Prof. [illegible]	Mr. Kiran K S

PRINCIPAL
KLECOP, Bengaluru
KLE UNIVERSITY'S
COLLEGE OF PHARMACY
2nd Block, Rajajinagar, Bengaluru-10

KLE UNIVERSITY'S
COLLEGE OF PHARMACY
2nd Block, Rajajinagar, Bangalore-

ATTESTED

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

भारतीय रेल न्यायिक

एक सौ रुपये Rs. 100

ONE

रु. 100 HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2020 ◑ XA 981977

Sub Treasury Officer
Hingna
03 DEC 2020
Sub Treasury Officer
Hingna

MEMORANDUM OF UNDERSTANDING

BETWEEN

DATTA MEGHE COLLEGE OF NURSING, NAGPUR, INDIA

AND

KAHER INSTITUTE OF NURSING SCIENCES, BELAGAVI

NOTARIAL REG.
ENTRY NO. 1179
DATE 14/12/2020

FOR

COLLABORATION IN THE FIELD OF

RESEARCH, EDUCATION, Study centre for running shared courses AND

Student & teacher exchange

Preamble:

This memorandum of understanding is made between the Datta Meghe College of Nursing, Nagpur and KAHER Institute of Nursing Sciences, Belagavi witnessed as follows:

ATTESTED

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

फक्त प्रतिज्ञापत्रासाठी(अनुच्छेद-४)

प्रतिज्ञापत्र कोणाकडे सादर करावयाचे

दत्ता मेघे नर्सिंग कॉलेज
वानाडोंगरी हिंगणा

99163

03/12/2020

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

ATTESTED

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

RECOGNISING the mutual interest in the fields of research, development, educational training, other facilities and dissemination of knowledge on long term non-commercial basis, and also,

RECOGNISING the importance of the role of institutes in promoting international collaboration and increased contribution to social development and services.

HEREBY agree to establish collaboration in terms of the research projects, education and student and teacher exchange during the pendency of MOU accordi to terms and conditions set out in the articles following hereunder,

The words "the two institutions" and "collaborating institutions" in the Memorandum of Understanding refer to the "Datta Meghe College of Nursing, Nagpur" and KAHER Institute of Nursing Sciences, Belagavi

Article-1: FIELD OF COLLABORATION

Collaboration between the two institutions may be established within any field related to science and technology of mutual interest and in particular research, health care professional education and patient care. Extension to other areas will be made through further amendments to the present Memorandum of Understanding.

Article-2: EXCHANGE OF STAFF AND STUDENTS

2.1 Faculty and students of either institute, who wish to undertake ort-term programme or field work/research work at the other institu will be assisted by the host institution in getting authoriza finding aocommodation, library and laboratory facilities provided the p umme is accepted by the home institution and by at least one supervis m each institution.

2.2 There is a possibility of twinning faculty and students ne two institutions in common research.

2.3 Parties will exchange proposals concerning the topics, per type of research, tests and periods of specific research reasonably ance of the proposed visit.

ATTESTED

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

2.4 The facilities available in the respective institutions shall be -nded for the patient care to the referred patients in the subsidized mar

Article-3: TRAINING OF DMCON STUDENTS

3.1 KAHER Institute of Nursing Sciences, Belagavi will provide ities for practical training of students of DMCON, Nagpur. This training be for a minimum of 6 working days. The training fees, travel and/or livi wances to these students will be provided by DMCON, Nagpur or stud elf. The selection of the student will be need based.

Similarly students from KAHER Institute of Nursing Sciences avi can also be sent for training to DMCON, Nagpur.

Article-4: JOINT SUPERVISION OF STUDENT PROJECT

4.1 As part of collaboration, the faculty of both institutes may joi pervise research project of students.

4.2 The details for projects of students will be worked out by pective persons of both institutions.

4.3 The student should first submit a project proposal which has to horized by both the institutions.

4.4 Both the institutes will hold intellectual property rights on any arch or project being jointly done.

4.5 Publication of the same will be done in joint collaborations

Article-5: RESEARCH PROJECTS

5.1 Efforts will be made to write and conduct research projects, tutions and provide information about on-going research activities oer to establish contacts and collaboration between professionals wo hin the same field.

5.2 Research projects and the composition of research teams wil ved by the both institutions. Efforts will be made to evaluate the r pating staff and the location of the research activity.

5.3 Each research project will be jointly lead by both institutions to r, who will be responsible for reporting on the project status.

ATTESTED

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

5.4 Both the institutes will hold intellectual property rights on any res... or project being jointly done.

5.5 Publication of the same will be done in joint collaborations

Article-6: INTELLECTUAL PROPERTY RIGHTS (IPR)

6.1 Information on research results and scientific materials (r... articles, books, patents) will be exchanged freely by both institutes and ... agreed provision of Intellectual Property Rights. All intellectual property sol... nceived and/or developed by DMCON during the course of this agreement s... owned by DMCON. All intellectual property solely conceived and/or ... ped by KAHER Institute of Nursing Sciences, Belagavi during the ... of this Agreement shall be owned by them. Intellectual property jointly ... and/or developed by DMCON and KAHER Institute of Nursing Sciences, ... will be jointly owned by DMCON and KAHER Institute of Nursing Scienc... elagavi. DMCON and KAHER Institute of Nursing Sciences, Belagavi agre... iborate towards the protection, if application of such intellectual property ... nercial or other purposes on mutually acceptable terms with equal shares.

Article- 7: FUNDING AND FINANCE

7.1 Information on research results and their application and scientific ... will be exchanged free of charge on returnable basis wherever pos...

Article-8: LINK MANAGEMENT AND ADMINISTRATION

Negotiation, implementation and co-ordination of the M... m of Understanding falls under the responsibility of both, the Director ... AHER Institute of Nursing Sciences, Belagavi and the Principal Dr. ...

The Memorandum of Understanding will take effect from th... ed by the Registrar of the DMCON, Nagpur and Registrar of the KA... ute of Nursing Sciences, Belagavi.

ATTESTED

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

Article-9 : GENERAL PROVISIONS

9.1 The two institutions will carry out joint research as a follow up to this Memorandum of Understanding. The activities must be carried out in accordance with appropriate laws and regulations existing in country and the DMCON

9.2 The two institutions shall initiate an exchange of research publications, publication lists and other official publications. This will be provided with adequate security as for as intellectual property laws are concerned as mentioned in article no 6.

9.3 All publications resulting from the collaboration between the two institutions will be mentioned in the scientific reports of the institutions. Likewise, this Memorandum of Understanding must also be mentioned in the formal presentations, which result from the collaboration under the terms of this Memorandum of understanding.

9.4 This Memorandum of Understanding is signed subject to appropriate authorizationon both sides.

9.5 KAHER Institute of Nursing Sciences, Belagavi will have (affiliation) recognized centre to the DMCON, deemed university and can initiate technical manpower training courses jointly with DMCON under the Deemed University.

Article-10 : NON-DISCLOSURE

10.1 In case of joint research and consultancy projects taken up by DMCON and KAHER Institute of Nursing Sciences, Belagavi no party will disclose any investigation to media / any unauthorized person from either in any form whether electronic/print without mutual consent and approval by coordination Committee.

Article-11: SETTLEMENT OF DISPUTES

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

ATTESTED

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

consent of both the parties, without reference to any tribunal o[illegible] t Nagpur only.

Article-12: VALIDITY PERIOD

12.1 This MOU shall be valid for a period of five years from the d[illegible] gning. At the end of validity period of the MOU, a fresh MOU with [illegible] ed terms may be considered for signing.

Registrar
DMCON, Nagpur
Maharashtra, India

Dr. Ranjit Ambad
Assistant Registrar (Off Campus)
DMIMSU (NAGPUR)

Dated: 14|12|2020

KLE Acaden[illegible]
& Research [illegible]
India

KLE [illegible]

Dated:

Principal
DMCON, Nagpur.
Datta Meghe College of Nursing
Hingna Road, Wan[illegible]
Nagpur - 4[illegible]
14|12|2020

Dated:

KAHER Institu[illegible]
Belag[illegible]

Date

SEAL OF NOTARY ARVIND D. MENDHE HINGNA DIST. NAGPUR (M.S.) Reg. No. 1112 GOVT. OF MAHARASHTRA

NOTARY ARVIND MENDHE Dist. NAGPUR Reg. No. 1112 GOVT. OF MAHARASHTRA

ATTE[illegible]
ARVIND D[illegible]
NOTA[illegible]
TAH HINGNA DIST

CANCELLED

CANCELLED

ATTESTED

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

MEMORANDUM OF UNDERSTANDING

BETWEEN

BULE HORA UNIVERSITY (BHU)

AND

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER)

Contact Information

BULE HORA UNIVERSITY (BHU)

P.O. Box 144,
Telephone: +251- 464430185
Fax:- 251- 464430355

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
Nehru Nagar, Belagavi, Karnataka, INDIA
Telephone:-+91(0)8312472303
Fax Number: +91(0)8312475103

OCTOBER - 2020

Bule Hora, Ethiopia

ATTESTED

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

सत्यमेव जयते

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Government of Karnataka

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Unique Doc. Reference	:	SUBIN-KAKA-SHCIL74845275541740S
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	:	BULEHORA UNIVERSITY BHU
Stamp Duty Paid By	:	KAHER INSTITUTE OF NURSING SCIENCES BELAGAVI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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

BULEHORA UNIVERSITY (BHU)

Ministry of Education, Ethiopia

Bule Hora Town, Oromia region

Ethiopia, East Africa.

ATTESTED

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

Preamble

This Memorandum of Understanding (MoU), is made and entered into as of 8th October, 2020.(Effective Date) by and between **Bule Hora University**, a Public higher education institute(hereinafter referred to as (BHU), with its principal place of business at Bule Hora, Ethiopia of the one part;

AND

KLE Academy of Higher Education and Research is a "Deemed To Be University" having KLE Institute of Nursing Sciences as one of its constituent unit, having its registered office at JNMC Campus, Nehru Nagar, Belagavi, Karnataka, India.

Whereas, Bule Hora University (BHU) is founded in 2008, Bule Hora University is a public higher education institution located in the medium city of Bule Hora town, Oromia Region, Ethiopia, East Africa. Officially accredited and/or recognized by the Ministry of Education, Ethiopia. University has started functioning in the campus of Bule Hora College of Teacher Education with a total of 243 regular and 116-weekend degree students and also within 72 academic staff and 164 admin staff in 4 faculties and 6 Departments in the 2011/12 academic year and transferred to its own campus in September 2012.

Currently, Bule Hora University has 200 programs (100 undergraduates, 83 Masters and 17 PhD) with strength of total 17,120 students (10,542 regular, 6578 extension, 16,368 undergraduates, 752 postgraduates). We have highly talented 1153 academic staff (both local as well as expatriate staff,mainly from India) and 3239 admin staff. Currently we are running eight colleges, namely College of Natural and Computational Sciences, College of Agriculture, College of Engineering and Technology, College of Social Science and Humanities, College of Business and Economics, College of Health and Medical Science, College of Informatics, College of Educational and Behavioural. We are also running one school and one institute namely School of Law and Institute of Gada and Cultural Study.

Bulel lora University (BHU) was established to play its part in the national efforts of bringing quality and excellence in teaching-learning, research, community services, administrative functions/good governance, connecting the development of cultural and natural resources with technology and its applications. Enhancing the quality level of university has been the

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

main target of BuleHora University (BHU) for achieving status of world Class University. The university believes that collaboration can enhance the quality of research and teaching through an exposure to a new perspective and experience of research and teaching. In doing so, BuleHora University (BHU) is developing international collaboration with many universities.

Whereas: KLE Academy of Higher Education and Research is a "Deemed To Be University" (KAHER) and KLE Institute of Nursing is affiliated to KAHER as a constituent unit. 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 and KLES Centenary Charitable Hospital.

KLE Academy of Higher Education and Research, 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 14 RANK among all Indian universities under teaching learning & resources(TLR) Category. The university adjudged as the fourth cleanest campus in the university 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

Whereas: BHU and KLE Academy of Higher Education and Research interested and willing 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.

Now therefore, the contracting parties have adopted this Memorandum of Understanding with the approval of their respective executive bodies to lay ground for effective institutional cooperation as follows:

ATTESTED

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

Article: 1

Areas of Collaboration

Cooperation under this Memorandum of Understanding (MoU) shall include, inter alia, and as appropriate, the following:

- Joint teaching arrangements for postgraduate as well as PhD Programs
- Joint supervision of postgraduate projects and PhD research
- Dual credential programs
- Student and faculty exchange visit
- Exchange academic information, publications and best practices.
- Assisting and facilitating Publications in JKIMSU and other reputed international journals.
- Both universities and the constituent Unit may allow/provide faculties to visiting scholars, to participate as adjunct professors if the need arises from either party
- Library and documentation exchange
- Exchange of pedagogical material
- Joint application for funding including development funds and research grants
- Participation in joint academic seminars and workshops
- Development and implementation of other joint activities addressing issues of mutual interest, designed to foster research and demand driven community service, technology transfer and education capacities in the locality.
- Any other collaborative efforts as may be determined by both parties.

ATTESTED

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

Article: 2

Joint work program

2.1 The two parties here to undertake to jointly solicit for funds, research grants, contributions, subscriptions and such related funds for the purpose of realizing any or all the objectives of the collaboration.

2.2. The aforementioned list of initial joint activities is not exhaustive and new activities addressing issues of mutual relevance may be proposed by the Partners whenever appropriate. Descriptions of new activities shall specify the respective responsibilities and financial obligations of the Parties and they will specify any additional sources of funds, as well as respective staff responsibilities. For implementing such joint activities, the Parties may agree on cooperation with other public or private organizations, including donors.

2.3 Both parties shall make rules governing the use of their respective facilities including laboratories, library and workshops where such facilities are used to conduct and of the function of this collaboration as specified in 'agreements of collaboration' regarding each individual project.

Article: 3

Exchange of information

3.1 The Parties shall regularly exchange information and seek complementarity and coordination regarding their relevant activities and programs;

3.2 The Parties may invite each other to participate in activities, working groups, conferences and seminars that are not directly part of this MoU but that may be relevant to it, in conformity with respective applicable rules.

Article:4

Financial Obligations

4.1 All activities to be developed and implemented under this MoU will be subject to the availability of funds, either from the Parties' own resources or from donors. The Parties will engage in joint resource mobilization from governmental and non-governmental funding

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Prof. Dr. V.A.KOTHIWALE
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and Research, BELAGAVI

sources, including (inter-)national donor organizations, private sector and philanthropic funds and non-governmental organizations, in accordance with relevant rules and procedures.

4.2 The descriptions and budgets of actions to be jointly undertaken will be part of separate activity based Agreement, which will refer to this MoU and be signed by the respective Parties involved including donors, if any, prior to the initiation of any activity.

4.3 Both institutions shall seek waiver of duty and value added tax applicable in their respective countries on any equipment and materials obtained from either country for use by students and staff participating in this collaboration. As a general rule, the title and custody of any equipment acquired in the course of the collaboration shall remain with the host institution upon the expiry of that particular project as specified in individual 'agreements of collaboration'.

Article: 5

Responsibilities- Both parties agree to:

5.1 Maintain regular communication and meet as deemed necessary in-person

5.2 Develop a plan for collaborative initiatives

5.3 Work in their area of framework to support initiatives.

Article:6

Intellectual Property

a) Where either party has any intellectual property rights in any material that is subsequently used by the parties in connection with this MOU, then those intellectual property rights remain vested in that party.

b) Copyright of information as well as any other intellectual property rights, developed jointly by Parties shall be jointly vested in the Parties concerned. Likewise the owners and authors of research initiatives will remain with the two parties; hence, the dissemination of finding and publication will be made with equal recognition of two

ATTESTED

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

institutions. Without the consent of the two organizations the data will not be used for any purpose without a prior permission of the two parties.

c) Intellectual property rights, in particular copyright on material such as information, software and designs, made available by any of the Parties to carry out the activities under this MoU shall remain with the originating Party;

d) Each party agrees to do such further things as may reasonably be required of it to give effect to the intentions of the parties regarding ownership of intellectual property rights as expressed in this clause (including, without limitation, by executing such assignments and licenses of intellectual property rights as may reasonably be required).

Article: 7

No Exclusivity

This MoU does not obligate either Party to work exclusively with the other on any project whosoever or constitute either Party an agent of the other.

Article: 8

Independence of Parties

Neither Party has the authority, either expressed or implied, to enter into any agreement, incur any obligations on behalf of, or commit the other Party in any manner whatsoever, except as is provided in this MoU.

Article: 9

Managing the Collaboration

The contact/focal section on the side of (BHU) in managing the collaboration is the Research and Community Service V/president office. The Counterpart on the side of (KAHER, KINS) would be Prof. Dr.Sudha A.Raddi, Principal KAHER, Institute of Nursing Sciences.

- The counterparts shall jointly define plan for collaborative activities and the modalities of monitoring the implementation of the activities articulated in the collaborative agreement
- The focal points regularly report to their respective top management on the outcomes of the collaborative engagement.

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ATTESTED

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

Article: 10

Effective Date, Amendments, and Termination

This MoU shall be effective when signed by both Parties for five years and can be renewed by a written consent of the parties. This MoU may be modified by mutual consent of all the Parties, in accordance with their respective rules and regulations. Such amendments shall enter into force one month following notifications of consent by the Parties. Either party may terminate this MoU at any time upon advance written notice to the other Party with such termination becoming effective upon the date set forth in such written notice.

IN WITNESS WHEREOF, the parties hereto, each acting through their duly authorized representatives, have caused this MoU to be signed in their names and delivered as on the day and date mentioned above.

Signatories	For and on Behalf of BuleHora University	For and On Behalf of KLE Academy of Higher Education And Research
Name	Dr. ChalaWataDereso	Prof. Dr. V. A Kothiwale
Position	President of BuleHora University	Registrar, KLE Academy of Higher Education & Research
Signature	ዶ/ር ጫላ ዋታ ዴሬሶ ፕሬዚዳንት	
Date	Chala Wata Dereso (PhD) President 8th October 2020	8th October 2020
Official stamp		REGISTRAR 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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Description	:	MEMORANDUM OF UNDERSTANDING M O U
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Stamp Duty Amount(Rs.)	:	500 (Five Hundred only)

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Shri Sai Credit Souhard Sahakari Niyamit, Chikodi Branch-Belagavi-3

Authorised Signature

MEMORANDUM OF UNDERSTANDING

Please write or type below this line

This **Memorandum of Understanding** ("MOU") is entered into this Day 12/11/2020 ,2020 **Between**

KLE Academy of Higher Education & Research (KAHER) having its registered office at Nehru Nagar, Belagavi, Karnataka – 590010, India, represented by Dr. V. A KOTHIWALE hereinafter referred to as **KAHER** which is a well- known and reputed institute conducting health/medical education and engaged in research activities, which expression shall unless repugnant to context in which it is used, includes his successor in office and assigns) of the **FIRST PART**

ATTESTED

Statutory Alert:
1 The authenticity of this Stamp certificate should be verified at www.shcilestamp.com/ using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2 The onus of checking the legitimacy is on the users of the certificate.
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V. A. KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

And

Dharma Foundation of India with its Registered Office at New Delhi (hereinafter referred as **"DFI"**);
(through **Dr. Alaknanda Banerjee**) the duly authorised representative and signatory **OF THE SECOND PART**

KAHER and DFI may hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

WHEREAS:
KAHER which is a deemed- to- be university established u/s 3 of the UGC Act 1956. **KIPT** (KAHER Institute of Physiotherapy), a constituent unit of KAHER, is a well- known and reputed institute conducting Physiotherapy education and engaged in research activities

AND WHEREASDFI is a non-profit organization established as a charitable trust based at New Delhi. It caters to the health, social and recreation needs & opportunities for aged people.

AND WHEREAS now **KAHER (KIPT)** and **DFI** wish to enter into an agreement for the purpose of providing a mutually beneficial arrangement for the purpose of updating, enhancing and further developing, on a mutual basis, the standard of healthcare education, research and Physiotherapy practice and promoting the exchange of information and provision of training and development in healthcare education & research.

This may include but not limited to acceptance of students for practical attachment, sharing of training material, faculty, development and running of specialized courses, collaboration in areas of research, training & industrial design and conducting clinical evaluation, study trials, CMEs, protocols and data analysis.

For each specific activity the financial and other deliverables will be jointly worked out and formalized through separate agreement as the case may be.

THE PARTIES AGREE as follows:

ARTICLE I
COLLABORATION

The Parties will collaborate in the manner described in the Schedule ("Collaboration").

ATTESTED

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

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ARTICLE V
CONFIDENTIALITY & PROPRIETARY BRANDING

A Party in receipt of Confidential Information from the other Party must not use or disclose the other Party's Confidential Information without that other Party's prior written consent other than (i) for the purposes of carrying out this MOU, provided any disclosure is only to such of the receiving party's personnel or to its related company and its personnel who need to know and who are made subject to the confidentiality requirements of this MOU or (ii) as required by law.

Neither Party may make any public announcement in relation to this MOU without first obtaining the approval of the other Party.

Confidential Information means (i) the subject and terms of this MOU and (ii) all information (in whatever form) disclosed by one Party to the other, whether before or after the date of this MOU but excludes information which (a) is or becomes public knowledge other than through a breach of this MOU (b) the recipient can show to the discloser's reasonable satisfaction to have been in the recipient's lawful possession prior to disclosure or (c) the recipient can show to the discloser's reasonable satisfaction to have been lawfully received from a third party not obliged to keep that information confidential.

Each Party shall not use any name, logo, trade name, trademark, service mark or other symbol associated with the other Party without the prior written consent of the other Party.

ARTICLE VI
ARBITRATION AND GOVERNING LAW

This agreement shall be governed by and construed in accordance with Indian law. Any dispute, controversy, or claim arising out of or in connection with this agreement, including any question regarding its existence, validity or termination, or the legal relationships established by this contract, shall be referred to and finally resolved by arbitration under the Arbitration and Conciliation Act, 1996. The number of arbitrators shall be one. The seat, or legal place, of arbitration shall be Belagavi. The language to be used in the arbitral proceedings shall be English. The governing law of this agreement is as set out above.

ATTESTED

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

IN WITNESS WHEREOF, the parties hereby affix their signatures on the date and place mentioned above.

Signed by)
Name: ALAKANANDA BANERJEE)
Designation: FOUNDER CHAIRPERSON .)
duly authorized to sign for and on behalf of:)
Dharma Foundation of India)
in the presence of :)
Name: KRISHNA CHATTERJEE

Signature:)

Signature

Signed by)
Name: DR. V.A. KOTHIWALE)
Designation: REGISTRAR, KAHER)
duly authorized to sign for and on behalf of:)
KIPT)
in the presence of :)
Name: Dr. SANJIV KUMAR

Signature:)

Signature

Office of the P.
KLEU Institute of Physics
Belgaum-590010

20 JAN 2020

Inward: 451

Signature

ATTESTED

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

ARTICLE II
COSTS OF COLLABORATION

No party shall be held liable, by the other party, for any of the cost incurred during the collaboration.

ARTICLE III
NON-BINDING NATURE OF MOU

Notwithstanding anything contained in this MOU, including the Schedule, to the contrary, the Parties agree that save for the provisions of this Article III (Non-Binding Nature of MOU) and Article II (Costs of Collaboration), V (Confidentiality & Proprietary Branding) and VI (Governing Law), this MOU has no legal or binding effect.

This MOU does not create any legal obligation to enter into any form of collaboration between the Parties and shall not be deemed to be an exclusive arrangement for either Party.

Notwithstanding anything hereinabove both the parties may mutually agree for further collaborations on more areas of Medical Education & research as per the terms and conditions to be entered through a detailed written agreement.

Unless earlier terminated in the manner described below, this MOU shall be effective for a period of **two (2)** years.

Either Party may terminate this MOU at any time by serving 1 month prior written notice to the other Party.

ARTICLE IV
ASSISTANCE, COOPERATION AND GOOD FAITH OF THE PARTIES

The Parties acknowledge that the attainment of the objectives of this MOU is dependent upon the joint efforts of both parties through mutual trust and confidence and conducted in good faith. In this regard, the Parties shall endeavor to make available to the other such assistance as may be reasonably necessary, as they mutually determine, to attain the objectives.

ATTESTED

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

SCHEDULE

Collaboration

- **Subject to contract &arrangements to bemade KAHER (KIPT) Deliverables, include, and are not limited to:**

    - To develop protocols which would focus on identifying needs and areas of rehabilitation and training for elders, women, children and patientsfor family members/community workers/doctors/nurses/paramedics/therapists in their home/workplace/hospital regarding treatment/handling of patients, and lay people to train as physiotherapists for public health.
    - Evaluate, assess, and work for the solutions to the identified problems. Develop mobile health solutions.
    - To develop workshop for patients/ elders/ children/ family members/community workersdoctors / therapists/ nurses / paramedics/ therapists to get oriented to the concepts developed.
    - To provide DFI with expertise, inhealthcare platform design, development and testing of new protocols and data analysis.
    - To Conduct Joint Research & Educational Projects.

- **Subject to contract & arrangements to be agreed DFI Deliverables to include and not limited to**

    - Provide students and professionals of KAHER (KIPT)an opportunity to have attachments with DFIforfurtherance of their training needs and for professional enhancement.
    - To conduct joint research & educational projects.
    - To collaborate with international partners of KAHER/DFI in a consultative or collaborative capacity on a project by project basis.
    - Provide clinical expertise available with DFI as and when required by KAHER (KIPT) such as faculty, protocol development,mobile health apps, etc.
    - To conduct workshop for patients/ elders/ children/ family members/community workers doctors / therapists/ nurses / paramedics/ therapists to get oriented to the concepts developed.
    - Develop projects with founders&staff/students at KAHER (KIPT)by investigating the state of the art around technology related to the challenge, establish design constraints, brainstorm design concepts, then design and manufacture prototypes
    - Evaluate, assess, and work for the solutions to the identified problems.

Details of collaboration in terms of sharing:

Both parties agree to the following terms & conditions with respect to sharing of funds/grants & publications credits in the projects undertaken jointly or where either party has provided substantial contribution in terms of logistical support, manuscript writing/editingetc.

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

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Memorandum of Understanding (MoU) for Academic Research and Development in Health Sciences and Knowledge Exchange with

KLE Academy of Higher Education and Research, Belagavi, Karnataka
www.kledeemeduniversity.edu.in
and
ICMR- National Institute of Traditional Medicine, Belagavi, Karnataka
www.icmrnitm.res.in

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

KLE Academy of Higher Education and Research, Belagavi, Karnataka
(KLE Deemed-to-be-University)
www.kledeemeduniversity.edu.in

Memorandum of Understanding (MoU) for Academic Research and Development in Health Sciences and Knowledge Exchange with

ICMR- National Institute of Traditional Medicine, Belagavi, Karnataka
(Formerly Regional Medical Research Centre, ICMR)
www.icmrnitm.res.in

Date of Renewal:

From: 06.01.2020
To : 05.01.2025

ATTESTED

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

Resource Development Notification F.9-19/2000-U.3(A) dated 13th April 2006 and imparting education in Under-Graduate/ Post-Graduate/ Super-specialty / Post-doctoral courses and Doctor of Philosophy (Ph.D) in the disciplines of Health Science viz. Medical, Dental, Pharmacy, Ayurveda, Physiotherapy and Nursing Science including Inter-disciplinary Studies/ Research. At present, there are eight constituent units under the ambit of the KLE University as detailed below:

1. Jawaharlal Nehru Medical College, Belgaum (Estd. 1963).
2. KLE VK Institute of Dental Sciences, Belgaum (Estd. 1985).
3. KLES College of Pharmacy, Belgaum (Estd. 1968).
4. KLES College of Pharmacy, Bangalore (Off-campus Centre) (Estd. 1976)
5. KLES College of Pharmacy, Hubli (Off-campus Centre) (Estd. 1985)
6. KLES Shri BMK Ayurveda Mahavidyalaya, Belgaum (Off-campus Centre) (Estd. 1933)
7. KLES Institute of Physiotherapy, Belgaum (Estd. 1994)
8. KLES Institute of Nursing Sciences, Belgaum (Estd. 1987)
9. KLES Dr. Prabhakar Kore Basic Sciences Research Centre, Belgaum (Estd. 2012)
10. KLES Homeopathic Medical College and Hospital Belagavi (Estd. 2018)

The bed strength of the Hospitals of the KLE Deemed-to-be-University is 2,600 which provides ample clinical material for various research studies. The KLE Deemed University's Dr. Prabhakar Kore Basic Science Research Centre is set up in an area of 10,000 sq ft and focuses on Molecular Biology (including stem cell research), Medical microbiology, Pharmaceutical Analysis and Natural product research. In addition, this Centre is established to gear-up the research capacity through a series of highly focused workshops that will create critical pool of scientists, thus, providing the edge to keep up with current research and also engage with institutions of excellence on an equal platform.

The KLE Deemed University Research Foundation has the unique distinction of being selected as one of the Global Network Sites under the aegis of National Institutes of Health, USA for Woman and Child Health. The Research Foundation is dedicated towards woman and child health.

Principles of Co-operation:

It is imperative that ICMR-NITM and KLE Deemed-to-be-University share common goals of working towards finding solutions of various communicable and non-communicable diseases through mutual co-operation by utilizing strength of respective organizations.

ICMR-NITM, Belagavi and KLE Deemed-to-be-University, Belagavi agree to develop their academic links especially in the fields of Health Care, Nutrition and Life Sciences under the Principles of mutual understanding, common interest and mutually complementary activities.

1. To work in the areas benefiting the community at large.
2. To identify common thrust areas of research keeping in mind the Millennium Development Goals and national priorities in the field of health sciences and health-care.

ATTESTED

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

8. Scientists of ICMR-NITM Belagavi and may deliver lectures in areas of their specialization to students of KLE Deemed-to-be-University as 'Visiting Faculty' on days and timings pre-arranged on mutual consent.

Duration and Termination of the MoU

1. This MoU is effective as of the date of signatures by the authorities of ICMR-NITM, Belagavi and KLE Deemed-to-be-University, Belagavi
2. This MoU is valid from the date of execution by the parties and shall remain in effect for FIVE Years, and thereafter can be renewed.
3. This MoU may be amended at any time by written mutual consent.
4. This MoU may be terminated by either party by the provision of written notice of termination not less than three months prior to the desired termination date. However, both parties agree that all continuing obligations to students, staff, funding bodies or other entities are met in full subsequent to the notice of termination.
5. The termination of this MoU shall not affect the rights or obligations of either party regarding any binding offer or firm obligation approved and agreed to either party prior to the termination date.
6. In event of any dispute/s arising between the parties hereto, it shall be endeavour of both the parties to first make an attempt to resolve the dispute amicably by mutual discussion and deliberation, failing which the dispute shall be amicably resolved through mutual discussion and deliberation, failing which the dispute shall be referred to arbitration. The Arbitration shall be conducted as per the provisions of arbitrator, to be appointed mutually by both the parties. The venue of arbitration shall be Belgaum. The language of arbitration shall be English. The award of the tribunal shall be final and binding on the parties.

Miscellaneous:

1. If any provision of this Memorandum is held by any court or the competent authority to be illegal, void or unforceable in whole or in part, this Memorandum shall continue to be valid as to the other provisions therefore and the remainder of the affected provision.
2. Nothing in this MoU constitutes or to be construed a party, partner, agent employee or representative of the other party. A party must not act independently of the other party and does not have the right or power of or pledge the credit of the other party without the prior written approval of the other party.
3. The parties agree to comply with all laws applicable within the jurisdiction of the signatories below.
4. Data generated through such collaborative research will be published in scientific journals jointly.

ATTESTED

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

3. To promote individual contacts among research scholars, students and faculty of both the institutions.

4. To provide opportunities for the faculty members, research scholars and students to use the expertise and facilities available in both the organizations.

5. To work jointly for the common research interests. This includes preparation and submission of proposals / protocols and their implementation by making use of the clinical material / facilities at KLE Deemed-to-be-University and ICMR-NITM, Belagavi.

6. To mutually acknowledge the experience, expertise and capabilities of ICMR-NITM, Belagavi and KLE Deemed-to-be-University and give due importance in collaboration, resource sharing and partnership.

7. To publish reports of sponsored projects / papers and disseminate results, with due credits to the contributors from the respective institutions.

8. To organize seminars and workshops to deliberate on important issues and also to organize training / sensitization programs for health and social sciences professionals.

9. To support the exchange of academic, research and training material to each other, available in the respective institutions.

10. To encourage any other activities that both the institutions agreed to be on mutual benefit.

Terms of Reference:

1. To jointly undertake research activities, submit grants proposals to various funding agencies.
2. Once MoU is signed, KLE Deemed-to-be-University shall grant, after due consideration of facilities and competencies, recognition to scientists at ICMR-NITM for Ph.D. Program.
3. Students of ICMR-NITM, Belagavi will be allowed to register for Ph.D. program of the KLE Deemed University and will also be eligible for scholarships and contingencies as stipulated by the University from time to time.
4. The Ph.D. program will be governed by the Rules & Regulations specified by the KLE Deemed –to-be-University which is in accordance with UGC Regulations, 2016 for Ph.D. Program which are to be mandatorily followed by all Universities.
5. The number of seats /intake can be decided by consensus each year before notification for admissions.
6. The Ph.D Supervisors may be from the sponsoring institution, while Co-Supervisors (Guide)/Co-Guides may be from either of the institutions, subject to fulfilling the criteria specified in Ph.D. Regulations by UGC.
7. Ph.D students working at KLE University will be allowed to utilize the facilities available in both the institutions at ICMR-NITM Belgaum and vice-versa depending upon requirements.

ATTESTED

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

IN WITNESS Whereof the parties hereto have executed this MoU or caused it to be executed in their names and on their behalf by their duty authorized representatives on the date set forth.

For NITM (ICMR), Belagavi

Signature:

Name:

Designation:

Date: 31th November 2020

For KLE Deemed University, Belagavi

Signature:

Name: Prof. Dr. V.A.KOTHIWALE

Designation: Registrar
KLE Academy of Higher Education and Research, BELAGAVI

Date: 10/11/20

Witnesses:

1. Dr. Basappa S Unger, Sci-E
2. Dr. Baraba Hegde, Sc-E
3. (S.G. PATIL)
4. 10/11/2020

6

ATTESTED

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

The respective University / Centre jointly recognize this MoU to mutually cooperate in the areas of advanced training and practical exposure in the field of Cleft & Craniofacial Surgery and Burns for the benefit of Post-Graduate students of M.Ch. students in Plastic & Reconstructive Surgery of both the Institutes.

PURPOSE / OBJECTIVE

The primary purpose of this MoU is to build training capacity for the M.Ch. students of the Departments. The MoU shall formally set out the terms of co-operative relationship between the parties, establish their respective roles, and facilitate the function of each party in relation to academic training.

Both the Departments agree to develop collaborative activities in academic areas of mutual interest / advanced practical training and as equal partners with reciprocity. All academic and research training events are expected to reflect the Post-Graduate students and faculty members in the area Cleft & Craniofacial Surgery and Burns.

The development and implementation of specific activities based on this MoU shall be negotiated and agreed upon with mutually accepted terms and conditions.

This MOU is agreed on the basis of cooperation between the Departments includes the following:

A. The Departments desire to provide training /education /academic collaboration for their students.

B. Each Department will depute its M.Ch. students to the other Department for a period of 15-30 days as per the need and availability.

C. Head of Departments of both the colleges shall be the Officers In-charge for this collaboration.

TERMS OF AGREEMENT

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

The term of this agreement shall be valid for a period of five years commencing from the date of signature hereof. This 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 witness whereof, the parties have executed this document by signing on the day of 19 May 2019.

Dr. Rajesh S.Powar,
Professor & Head
Department of Plastic Surgery,
KLE Medical College, BAILHR

Dr. Ramesh K.T
Professor & Head
Department of Plastic surgery and Burns,

ATTESTED

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

MEMORANDUM OF UNDERSTANDING

BETWEEN

Department of Plastic & Reconstructive Surgery,
KAHER's J.N. Medical College,
KLE Academy of Higher Education & Research (A Deemed University u/s 3 of the UGC Act 1956 vide Government of India notification No.9-19/2000-U.3A)
Belagavi-590010, Karnataka, India
herein represented by
Dr. Rajesh S. Powar,
Professor & Head, Department of Plastic & Reconstructive Surgery,
AND
Prof.(Dr.) K. V. Sahasranam MD, DM, FACC, FCSI
Chief of Medical services
Baby Memorial Hospital, Calicut,
Kerala State.

The **Department of Plastic & Reconstructive Surgery, J.N. Medical College,** Belagavi, Karnataka, India and the **Department of Plastic & Reconstructive Surgery Baby Memorial Hospital Ltd, Calicut** recognize the benefits to their respective Institutes from the establishment of collaborations and proceed to have a Memorandum of Understanding (MoU). Both the independent institution / centre are committed to mutual and common goals of generating new knowledge towards academic collaborations in Plastic & Reconstructive Surgery.

PREAMBLE:

The Department of Plastic & Reconstructive Surgery was established at the J.N. Medical College, Belagavi in the year 1998. It was recognized to start M.Ch. programme by the Medical Council of India in the year 2009. This department was recognized by the Smile Train, USA to perform surgeries for Cleft Lip & Palate deformity in the year 2001. Since then, the department has performed close to 10,000 Cleft surgeries. The J.N. Medical College is a constituent unit of the KLE Academy of Higher Education & Research, which is a Deemed University u/s 3 of the UGC Act 1956 vide Government of India notification No.9-19/2000-U.3A. The University has been accredited with **'A' Grade** by National Assessment and Accreditation Council (NAAC) in the 2nd Cycle and has been placed in **Category 'A'** by the Ministry of Human Resource Development (MHRD), Government of India.

The Department of Plastic & Reconstructive Surgery at the Baby Memorial Hospital, Calicut, Kerala State is one of the oldest and most well established. It is recognized for the DNB. programme since 2014. The Department also has a 8 bedded Burns Ward at the Baby Memorial Hospital Ltd, Kozhikode, Kerala.

ATTESTED

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

The respective University / Centre jointly recognize this MoU to mutually cooperate in the areas of advanced training and practical exposure in the field of Cleft & Craniofacial Surgery and Burns for the benefit of Post-Graduate students of DNB. students in Plastic & Reconstructive Surgery of the Baby memorial hospital ltd..

PURPOSE / OBJECTIVE

The primary purpose of this MoU is to build training capacity for the post graduate students of the Departments. The MoU shall formally set out the terms of co-operative relationship between the parties, establish their respective roles, and facilitate the function of each party in relation to academic training.

Both the Departments agree to develop collaborative activities in academic areas of mutual interest / advanced practical training and as equal partners with reciprocity. All academic and research training events are expected to reflect the Post-Graduate students and faculty members in the area Cleft & Craniofacial Surgery and Burns.

The development and implementation of specific activities based on this MoU shall be negotiated and agreed upon with mutually accepted terms and conditions.

This MOU is agreed on the basis of cooperation between the Departments includes the following:

A. The Departments desire to provide training /education /academic collaboration for their students.
B. The Department of Plastic & Reconstructive Surgery of the Baby memorial hospital ltd. will depute its M.Ch/DNB. students to the other Department of Plastic & Reconstructive Surgery, J.N. Medical College, for a period of 15-30 days as per the need and availability.
C. Head of Departments of both the colleges shall be the Officers In-charge for this collaboration.

TERMS OF AGREEMENT

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

The term of this agreement shall be valid for a period of **five** years commencing from the date of signature hereof. This 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 witness whereof, the parties have executed this document by signing on the day of 1st November 2020.

Dr. RAJESH S. POWAR
M.S., M.Ch., D.N.B.
Professor & Head
Department of Plastic & Reconstructive Surgery
J.N. Medical College

Dr. Rajesh S.Powar,
Professor & Head

Baby Memorial Hospital Ltd.

ATTESTED

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

Prof.(Dr.) K. V. Sahasranam MD, DM, FACC, FCSI
Chief of Medical services

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

JeevanRekha Ayurveda Multispecialty Research Center,

Plot No 87, Snehawardhini Housing Society,

Behind Trimurty Chowk, Jawahar Colony,

Aurangabad -05, Maharashtra (India)

For

Establishment of Specialty Consulting Unit, Research, Training and Collaborative Programs on Education For Faculty & Students

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

JeevanRekha Ayurveda Multispecialty Research Center,
Aurangabad, Maharashtra

This Memorandum of Understanding (MoU) is executed on this the 10th day of April 2019 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, (hereafter referred as '**KLE BMK**', which expression shall, unless repugnant to the subject or thereof, be deemed to include and mean to its nominees, successors in office and permitted substitutes or assigns) on **ONE PART AND** JeevanRekha Ayurveda Multispecialty Research Center, Aurangabad, Maharastra, Plot No 87, Snehawardhini Housing Society, Behind Trimurty Chowk, Jawahar Colony, Aurangabad -05, Maharashtra (India) (hereinafter referred as "JEEVAN REKHA" which expression shall mean and include its assignees and successors in office) on the **OTHER PART.** Either or both of them be referred collectively as a "party" or "Parties" respectively as the context demands.

Background:

KLE Academy of Higher Education & Research Belagavi, Karnatakaisa 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. KLEAyurveda Hospital & Medical Research Center has been accredited by NABH, the first Ayurveda institute to get NABH accreditation in Karnataka. Shri B.M.Kankanawadi Ayurved Mahavidyalaya was 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

ATTESTED

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

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CCIM for11 PG departments with 65 seats and 100UG seats.It is also conducting PhD program in Ayurveda and Interdisciplinary areas of KAHER PG Certificate Programs on various domains like Vajeekarana, Ksharasutra, Panchakarma, Herbal Drug Research, Ayurgenomics etc. It has good infrastructure for teaching as wellas 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.

JeevanRekha is dedicated to Ayurveda in the area of authentic research supported by in-house sophisticated and fully equipped research laboratory backed by a team of qualified professionals passionately engaged in their value adding contributions. After long & sincere efforts they have successfully cup up with this project for modern physicians in the specific areas of health care like medicine, pharmacology& biochemistry presented with modern technological approach to create a space for better and easy understanding of Ayurveda.

ARTICLE I: OBJECTIVE

The objective of this agreement is to develop scientific, academic and educational co-operationbetween two institutes, establish a specialty consultation research unit and cooperate for providing a range of higher educational and scientific activities. The main intent of this initiative is to establish the specialized metabolic disorder care unit and to perform collaborative research project in developing newer management solutions in the field of Indian system of Medicine (Ayurveda) and collaborative activities between the two Institutions.

Specialty consultation includes specified investigation profile, specific clinical examinations and thorough analysis of Prakruti and instituting exclusive and unique treatment protocol.

In collaborative research activities, the PG scholars will be deputed for research works and DrMukundsabnis.Dr.Sabnis shall be assigned as Co guide for suitable upcoming research works of Post graduate scholars of various departments. JeevanRekha will take up research designs in multi centric approach.

ATTESTED

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

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 'JeevanRekha Research Unit, through such activities or programs as: *Regarding Health Care Services.*

1) KLE BMK provides space and Customized products and JR will be requested to dispatch as per the Patient's Prakruti Analysis done by Consultant and as per the provisions of Drugs and Cosmetic Act 1940, under the Section 33(EE) of C
2) One consultant will be nominated from KLE to look after the unit and to get trained protocol of management.
3) KLE BMK conducts regular camps and TV/Radio programs etc for advertising the extended facility in specialty center. Expenses will be borne by KLE itself. JeevanRekha will not contribute any amount.
4) JeevanRekha will give guidelines in establishing the specialty unit
5) JeevanRekha have to depute consultant to the said unit once in a month. Travelling expenses of the consultants shall be borne by JeevanRekha.
6) JeevanRekha will introduce and implement standard protocol developed by them and train nominated consultants for management.
7) IPD collection through this unit will be on sharing basis (As per approved policies of KLE Ayurveda Hospital). JeevanRekha has no role in collection of amount of Consultation Charges of OPD. The ratio of medicines supplied from JeevanRekha shall be 60% (JeevanRekha)- 40% (KLE BMK). Price List will be provided as and when updated.
8) The College/its doctors shall not be at liberty to change the location of Medical practice other than which is mentioned in the present agreement unless otherwise agreed by mutual consent and in case of such unilateral change, the present agreement stands terminated.
9) The College/its doctors shall have to observe model code of conduct which may be prescribed from time to time in addition to the professional ethics prescribed by India Medical Council in order to have fair, transparent and honest dealing with registered persons joining OMP.

Regarding Education and research activities:

10) Syllabus prescribed by JeevanRekha will be shared with KLE and it will be processed for University approval and then training will be scheduled as per the syllabus.
11) Fellowship programs will be for a duration of 02 years which includes online classes and regular classes, didactic lectures, demonstrations, hands on training and group activities.
12) Certificate courses will be for duration of 06 months which shall include Regular classes, didactic lectures, demonstrations, hands on training and group activities.

ATTESTED

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

13)Dr. Mukund Sabnis shall be assigned as Co guide for suitable upcoming research works of Post graduate scholars of various departments.

14) The courts at**Belagavi**shall be the jurisdictional courts for redressal of disputes, if any arises between The College/its doctors and JeevanRekha during in relation to this MOU agreement.

15)It will be a reserved prerogative of JeevanRekha to extend special schemes which may involve price concession to the end users in particular area of its choice and the College/its doctors shall not claim such benefit as a matter of his right.

16) Signing this MOU means parties have unconditionally agreed for clinical practice on the addressmentioned above in this MOU.The College/its doctors found practicing in other areas, the fact itself may lead to termination of this MoU.

ARTICLE III: FINANCIAL ARRANGEMENTS

- The financial arrangements to meet the expenses incurred for the said 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 contained in paragraph (a) above, the intellectual property rights in respect of any technological development and/or any products / services developed.

(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.

ATTESTED

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

ARTICLE V: CONFIDENTIALITY

A. Each Party undertakes to maintain confidentiality and secrecy of documents, information and other data received or supplied to, the other Party during the period of 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 on 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, a dispute arose between the parties and is not resolved through negotiation or by adopting amicable measures, the matter shall be settled through Arbitration and the Arbitrator will be appointed with the mutual consent of both the parties.

ARTICLE VII: COMMENCEMENT, DURATION AND TERMINATION

This understanding shall come into force 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 MOU may be terminated by either party by giving 90 (ninety) days written notice to the other party. Such notice shall be issues before the beginning of academic year, and the MOU would be terminated automatically at the end of the notice period.

The termination of the Understanding shall be conditional. The students/ faculty who have already been enrolled in any of the courses / research programs shall be entitled to complete their respective courses/ research programs conducted by the **'KLE BMK'** and **'JEEVAN REKHA'**and be eligible to appear assessment and 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 the Parties:

a) **Common Responsibilities**

i. 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.

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

iii. Both parties understand that all financial arrangements will have to be negotiated and shared depending on 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 collaborative activities, implementation and conceptualization
b. Providing basic infrastructure for establishing unit and necessary information and action
c. Suggesting necessary modifications and new requirements

c) **Roles & Responsibilities of JeevanRekha Ayurveda Multispecialty Research Center, Aurangabad.**

1) JeevanRekha will give guidelines in establishing a specialty unit
2) JeevanRekha have to depute consultant once in a month. Travelling expenses shall be borne by JeevanRekha.
3) JeevanRekha will introduce and implement standard protocol developed by them and train nominated consultants for management.

ATTESTED

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

Miscellaneous:

- A co-ordination committee consisting of the followingmembers will monitor the academic and collaborative research programs and other related operational activities.
- Dr. B.Sreenivasa Prasad, Shri B.M. Kankanawadi Ayurved Mahavidyalaya, a Constituent unit of KAHER Belagavi, Karnataka.
- Dr. Mukund Sabnis, JeevanRekha Research Unit and Hospital, Aurangabad, Maharashtra
- Dr. Ashok Patil, Professor and HOD, Department of Swasthavritta, Shri B.M.Kankanawadi Ayurved Mahavidyalaya, a Constituent unit of KAHER Belagavi, Karnataka.

c) **Coordinators of each center**

At KAHER Shri B.M.Kankanawadi Ayurved Mahavidyalaya, Principal will oversee the implementation of the Memorandum of Understanding.

At Jeevanrekha Research Hospital, Aurangabad, Maharashtra Dr. Mukund Sabnis will administer 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 **'JeevanRekha'**

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

Dr. B. Sreenivasa Prasad
Principal,
Shri B. M. K Ayurved Mahavidyalaya,
A constituent unit of KLE Academy of Higher Education & Research
(Deemed-To-Be-University)
Belagavi - 590003
Karnataka (India)

Sealed & signed for and on behalf of

Dr. Mukund Sabnis
Proprietor
JeevanRekha Ayurveda Multispecialty Research Center, Aurangabad, Maharashtra, Plot No 87, Snehawardhini housing society, Behind Trimurty Chowk, Jawahar Colony, Aurangabad -05, Maharashtra (India)

in the presence of

(Dr. Ashok Patil)

in the presence of

(Dr. Sangeeta Deshpande)

ATTESTED

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

KLE COLLEGE OF PHARMACY, BELAGAVI
(Recognized by PCI, AICTE & Accredited by NBA & 'A' grade By NAAC)
A constituent Unit of KLE Academy of Higher Education and Research
[Under section 3UGC Act, 1956 vide Govt. of India Notification No. F.9-19/2000-U.3 (A)]
Nehru Nagar, Belagavi – 590 010, Karnataka, India
Phone: 0831-2471399 Fax: 0831-2472387 Web: http://www.klepharm.edu E-mail: principal@klepharm.edu

Date: 25-09-2019

Memorandum of Understanding

This Memorandum of Understanding (MOU) between **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 of the One Part.

And

ARAR Pharmaceutical Research Centre Pvt. Ltd., Plot No. 351, KIADB, Kanabargi Industrial Area, Auto Nagar, Belagavi represented by Mr. Ramdas D. Raikar, Managing Director, ARAR Pharmaceutical Research Centre Pvt. Ltd., Belagavi of the one part.

Aims and Objectives of the MOU

1) By entering into this MOU the Institute and ARAR Pharmaceutical Research Centre agree to set up a frame work to encourage and develop collaboration between ARAR Pharmaceutical Research Centre, 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 Institute and ARAR Pharmaceutical Research Centre by developing collaborative research projects that utilizes the expertise and the environment of both ARAR Pharmaceutical Research Centre 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.

ATTESTED

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

KLE COLLEGE OF PHARMACY, BELAGAVI
(Recognized by PCI, AICTE & Accredited by NBA & 'A' grade By NAAC)
A constituent Unit of KLE Academy of Higher Education and Research
[Under section 3UGC Act, 1956 vide Govt. of India Notification No. F.9-19/2000-U.3 (A)]
Nehru Nagar, Belagavi – 590 010, Karnataka, India
Phone: 0831-2471399 Fax: 0831-2472387 Web: http://www.klepharm.edu E-mail: principal@klepharm.edu

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 relating to 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.

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

PRINCIPAL
KLE College of Pharmacy
BELAGAVI - 10

KLE COLLEGE OF PHARMACY BELAGAVI 590 010.

Signed on behalf of
ARAR Pharmaceutical Research
CentreAuto Nagar, Belagavi

ATTESTED

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

ARAR
Pharmaceutical Research Centre Pvt. Ltd.

Corp : off : 1st Floor, Bagi Complex, Maruti Galli, Belagavi-590 001.
Email : ararpharma@gmail.com Ph : (Off.) 4210889
Website : www.ararpharma.com

Ref. No. : 65/0/ARAR/19-20

Date : 25-09-2019

Memorandum of Understanding

This Memorandum of Understanding (MOU) between **ARAR Pharmaceutical Research Centre Pvt. Ltd., Plot No. 351, KIADB, Kanabargi Industrial Area, Auto Nagar, Belagavi**, represented by Mr. Ramdas D. Raikar, Managing Director, ARAR Pharmaceutical Research Centre 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 of the One Part.

Aims and Objectives of the MOU

1) By entering into this MOU the Institute and ARAR Pharmaceutical Research Centre agree to set up a frame work to encourage and develop collaboration between ARAR Pharmaceutical Research Centre, 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 Institute and ARAR Pharmaceutical Research Centre by developing collaborative research projects that utilizes the expertise and the environment of both ARAR Pharmaceutical Research Centre 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.

ATTESTED

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

ARAR
Pharmaceutical Research Centre Pvt. Ltd.

Corp : off : 1st Floor, Bagi Complex, Maruti Galli, Belagavi-590 001.
Email : ararpharma@gmail.com Ph : (Off.) 4210889
Website : www.ararpharma.com

Ref. No. : 65/0/ARAR/19-20

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 relating to 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.

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

PRINCIPAL
KLE College of Pharmacy
BELAGAVI - 10.

KLE COLLEGE OF PHARMACY
BELAGAVI
590 010.

Signed on behalf of
ARAR Pharmaceutical Research Centre Pvt. Ltd., Plot No. 351, KIADB, Kanabargi Industrial Area, Auto Nagar, Belagavi

ATTESTED

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

KLE COLLEGE OF PHARMACY

Vidyanagar, HUBBALLI-580 031, Karnataka

A constituent unit of

KLE Academy of Higher Education & Research, Belagavi

(Deemed-to-be-University)

✆ : 0836-2373174, 🖷 : 0836- 2371040, 🌐 : http://www.klescoph.org, ✉ : principal.klescoph@gmail.com

✉ : principharmhbl@kledeemeduniversity.edu.in

Ref. No. : KLESCOPH|MOU|2020-21|495 Date : 08|10|2020

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding signed on 8th day of October, 2020 between **Party-1: KLE College of Pharmacy,** Vidyanagar, Hubballi – 580 031 and **Party-2: Apollo Pharmacy**, Unit of Apollo Hospitals, Enterprises Ltd., No.13/2, EXH Building, Sigasandra, Hosur Road, Bengaluru – 560 068.

Party-1's Role:

1) Provide infrastructure and other facilities necessary to conduct campus interview.
2) Communication with the students regarding vacancy and display of advertisement of the same in the College premises.
3) Share professional information from Party-1 to Party-2.

Party-2's Role:

1) Give training for the eligible students of Party-1 as per the norms of the Party-2.
2) Recruit the eligible students of Party-1 as per the norms of the Party-2.
3) Provide copy of appointment and joining letter of the selected candidates to the Party-1.
4) Share any other related professional updates as may be required from Party-1 to Party-2.

This Memorandum of Understanding shall be operation ten years from the date of signing and may be amended if required in agreement with the both the parties.

Signature with Seal

Party-1:

On behalf of KLE College of Pharmacy, Hubballi – 580 031.

Dr. Alim Viswanatha Swamy
Principal
KLES College of Pharmacy
A constituent unit of KLE Academy of Higher Education & Research
Vidyanagar, HUBBALLI-580 031

Party-2:

On behalf of Apollo Pharmacy, Bengaluru – 560 068.

Shri.N.Sreedhar Reddy
H.R. Senior Manager

Witness-2:
Shri.Lokeshwara S.N.

ATTESTED

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

KLE COLLEGE OF PHARMACY

Vidyanagar, HUBBALLI-580 031, Karnataka

A constituent unit of

KLE Academy of Higher Education & Research, Belagavi

(Deemed-to-be-University)

✆ : 0836-2373174, 🖷 : 0836- 2371048, 🌐 : http://www.klescoph.org, ✉ : principal.klescoph@gmail.com

✉ : princpharmhbl@kledeemeduniversity.edu.in

Ref. No. : KLECOPM/MOU/2020-21/696 Date : 14/12/2020

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding on 15th day of December, 2020 between the Wallace Laboratories Pvt. Ltd., K.I.A.D.B. Industrial Area, Belur, Dharwad – 580 011, engaged in the field of manufacturing quality pharmaceuticals formulations here in called Industry represented by Mr.R.B.Rayanagoudar, Deputy General Manager – Plant on one part.

And

KLES College of Pharmacy, Hubballi, which is established 1985 carrying on Teaching, Training and Research, herein called Institute represented by Dr.AHM Viswanatha Swamy, Principal on the other part.

Aims and objectives of the Memorandum of Understanding:

The aim of Memorandum of Understanding is to set up a frame work to encourage and develop collaboration between Industry and Institute in the areas of mutual interest in the field of phytochemical research and following are specific objectives:

- To rise the research profile of both Industry and Institute by developing collaboration research projects that utilize the expertise and environment of both Industry and Institute.
- To provide an opportunity to students & faculty to learn and develop specific research skills.
- To explore the possibility of students' placements in the industry based on needs and requirements.
- To exploit the synergy arising from joint initiatives to improve the Industrial training of students.

Contd ..... 2.

ATTESTED

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

Indocoar Pharma Private Limited

Registered & Marketing Office
No. 10, Amarajyothi Layout, 1st Main Road,
Geddalahalli, Sanjaynagar,
Bangalore - 560 094 (INDIA)

Tel +91-80-23413783 / 23512751 / 23512750 / 23410235
Fax +91-80-23513103
Email mcah@vsnl.com mfg@indocoar.com
Website www.indocoar.com

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding on 07th day of October, 2020 between the Indocoar Pharma Pvt Ltd., Chalamatti engaged in the field of manufacturing quality pharmaceuticals formulations herein called Industry represented by Manager on one part.

And

KLES college of pharmacy, Hubli which is established 1985 carrying on Teaching, Training and Research, herein called Institute represented by Dr Vishwanath Swamy, Principal on the other part.

Aims and objectives of the Memorandum of Understanding

The aim of Memorandum of Understanding is to set up a frame work to encourage and develop collaboration between Industry and Institute in the areas of mutual interest in the field of phytochemical research and following are specific objectives:

- To rise the research profile of both Industry and Institute by developing collaboration research projects that utilize the expertise and environment of both Industry and Institute.
- To provide an opportunity to students & faculty to learn an develop specific research skills.
- To exploit the synergy arising from joint initiatives to improve the Industrial training of students.
- To explore the possibility of students' placements in the industry based on needs and requirements.

This Memorandum of Understanding shall be operation for period of 05 years from the date of signing.

Signed on behalf of
Indocoar Pharma Pvt Ltd.
CHALAMATTI.

INDOCOAR PHARMA PVT. LTD.

Mr.Darur. S.H. 9448281742

Signed on behalf of
KLES College of Pharmacy,
Hubli.

(Dr. Vishwanath Swamy)

Principal.

ATTESTED

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

KLE COLLEGE OF PHARMACY

Vidyanagar, HUBBALLI-580 031, Karnataka

A constituent unit of

KLE Academy of Higher Education & Research, Belagavi

(Deemed-to-be-University)

✆ : 0836-2373174, 🖷 : 0836- 2371048, 🌐 : http://www.klescoph.org, ✉ : principal.klescoph@gmail.com

✉ : princpharmhbl@kledeemeduniversity.edu.in

Ref. No. : KLESCOPH/Mou/2020-21/696 Date : 14/12/2020

This Memorandum of Understanding shall be operation for period of 03 years from the date of signing.

WALLACE LABORATORIES PVT. LTD. BELUR DHARWAD

Signed on behalf of
Wallace Laboratories Pvt. Ltd
Dharwad

(Mr. R. B. Rayanagoudar)
Deputy General Manager – Plan

KLES COLLEGE OF PHARMACY HUBBALLI 580031

Signed on behalf of
K.L.E. College of Pharmacy,
Hubballi

(Dr.AHM Viswanatha Swamy)
Principal

ATTESTED

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

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सत्यमेव जयते

Certificate No.	:	IN-DL95066404354917S
Certificate Issued Date	:	19-Oct-2020 04:09 PM
Account Reference	:	IMPACC (IV)/ dl860303/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL86030397054850541191S
Purchased by	:	KAHER KLE INSTITUTE OF PHYSIOTHERAPY
Description of Document	:	Article Bond
Property Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KAHER KLE INSTITUTE OF PHYSIOTHERAPY
Second Party	:	CAPRI INSTITUTE OF MANUAL THERAPY
Stamp Duty Paid By	:	KAHER KLE INSTITUTE OF PHYSIOTHERAPY
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

.....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 – 590010, 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

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

AND

This Agreement is executed at Belagavi on this 21st day of Oct, 2020 by and 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 179, Jagriti Enclave, Vikas Marg Delhi, India Pin 110092 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 250 certificate 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;
KLEU 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.

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

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. Develop academic program, Certificate in Orthopedic Manual Therapy "COMT" and 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 programmes for funding by internal, national and international agencies;
4. Design and develop outreach activities and programmes for various mutually identified goals of CIMT and KAHER;
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;

ATTESTED

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

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 musculoskeletal dysfunction within the scope of physical therapy;

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.
2. Within the broad framework of the MoU, KAHER and CIMT can develop joint research, academic or scientific programme, exchanges, development of facilities, etc.
3. Any financial commitment for joint activities under this MoU shall be subject to the approval by the competent authority of the respective organization.
4. 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.
5. The visitors will be bound by the rules and regulations as well as code of conduct of the host institution.
6. 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.
7. 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.**
8. The Coordination Committee will formulate action plans at its meetings and communicate for information and necessary approvals by the concerned authorities.

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

9. 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.

10. LIAISON AND SUPERVISION:

10.1 The Principal of the Faculty of Physiotherapy, KAHER will look after the operation, supervision and follow up of the program. And he will look after : Registration and enrollment of students, communication with the Capri Institute of Manual Therapy regarding the said training program (COMT); and Supervision of assessment, skill development and monitoring online discussion.

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.

D: 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 and **Dr. Bhini Semwal (PT)** MPT, MIAP, COMT, CMP from the Capri Institute of Manual Therapy will serve as lead faculty 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.
7. All expenses related to food and travelling of CIMT's faculty will be born CIMT.
8. Study material to course participants will be provided by CIMT as mentioned in Annexure-II.
9. KLEU will provide decent accommodation within its campus to the visiting faculties of CIMT, and all expenses related to accommodation will be borne by KAHER.
10. Hostel facility to course participants will be provided by KAHER in its campus against payment done by course participants directly to KAHER.
11. Advertisement of the COMT course will be done by CIMT and KAHER. All expenses for the advertisement done by CIMT will be borne by CIMT directly to the respective vendor and All expenses for the advertisement done by KAHER will be borne by KAHER directly to the respective vendor.
12. KAHER will provide all the infrastructural, logistic and facilities for the smooth conduction of COMT in its campus.
13. Along with faculties of CIMT, Faculties of KAHER will also be responsible for providing training, education, skill transfer, actively participating in research and discussion to course participant of COMT for the smooth conduction of this course in its campus.

ATTESTED

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

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 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.

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 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 programmes and faculty and students exchange. Hence any question, doubt or

ATTESTED

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

14. Criteria for completion of the COMT program by every candidate shall be as follows:

a) securing 75% attendance of all training work and clinical rotation;
b) completion of case presentation and assignments; and
c) Obtaining a minimum of 50% passing grade in the written and 50% passing grade in the practical tests.

15. The certificate will be issued jointly in the name of Capri Institute of Manual Therapy and the Faculty of Physiotherapy, KAHER. The Dean & Principal of KAHER along with the Director Capri Institute of Manual Therapy will sign the Certificate. Transcript will be signed by Principal, Faculty of Physiotherapy along with Director, Capri Institute of Manual Therapy, New Delhi.
16. 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.
17. The KAHER 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, where after, 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 instruction and eligibility for Certificate of all enrolled students will be 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.

ATTESTED

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

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.

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
Name: Chanchal Rani
Address: A-64, Hauz Apartment
Delhi - 110032

For and on behalf of KAHER

Registrar

Seal

Witness 2
Name:
Address: KLE IPT Belagavi-10

For and on behalf of CIMT

Director
Dr. Deepak Kumar
Seal

For Capri Institute of Manual Therapy
(A Unit of C.H.C.R.I. (P) Ltd.)

Director Director

ATTESTED

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

SCHEDULE
Annexure II
Fee Structure and Sharing

COMT 3 months Course offered by CIMT, Delhi & KLE Belagavi	Per Participants (Indian Delegates	
	Fee Collected by Capri	Fee Collected by KLE
Expences / fee		
Study material	3500	XX
Air fare & Transportation (Two Teachers X 4 Times)	4000	XX
Food & Local Transportation	500	XX
Coordinator fee (to be paid by Capri to faculty of KLE)	1000	XX
Advt of the course	1000	XX
Accommodation of teachers to be provided by KLE at its Guest House		
Indian Participants Tution Fee	20000	20000
Total	30000	20000
Indian Participants Total Fee 50000		

COMT 3 months Course offered by CIMT, Delhi & KLE Belagavi	Per Participants (NRI Delegates)	
	Fee Collected by Capri	Fee Collected by KLE
Expences / fee		
Study material	70USD	XX
Air fare & Transportation (Two Teachers X 4 Times)	80USD	XX
Food & Local Transportation	10USD	XX
Coordinator fee (to be paid by Capri to faculty of KLE)	25USD	XX
Advt of the course	15USD	XX
Accommodation of teachers to be provided by KLE at its Guest House		
NRI Participants Tution Fee	500USD	500USD
Total	700USD	500USD
NRI Participants Total Fee 1200 USD		

COMT 3 months Course offered by CIMT, Delhi & KLE Belagavi	Per Participants (Foreign Delegates)	
	Fee Collected by Capri	Fee Collected by KLE
Expences / fee		
Study material	70USD	XX
Air fare & Transportation (Two Teachers X 4 Times)	80USD	XX
Food & Local Transportation	10USD	XX
Coordinator fee (to be paid by Capri to faculty of KLE)	25USD	XX
Advt of the course	15USD	XX
Accommodation of teachers to be provided by KLE at its Guest House		
Foreign Participants Tution Fee	750USD	750USD
Total	950USD	750USD
Foreign Participants Total Fee 1700 USD		

ATTESTED

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

HP LaserJet Pro

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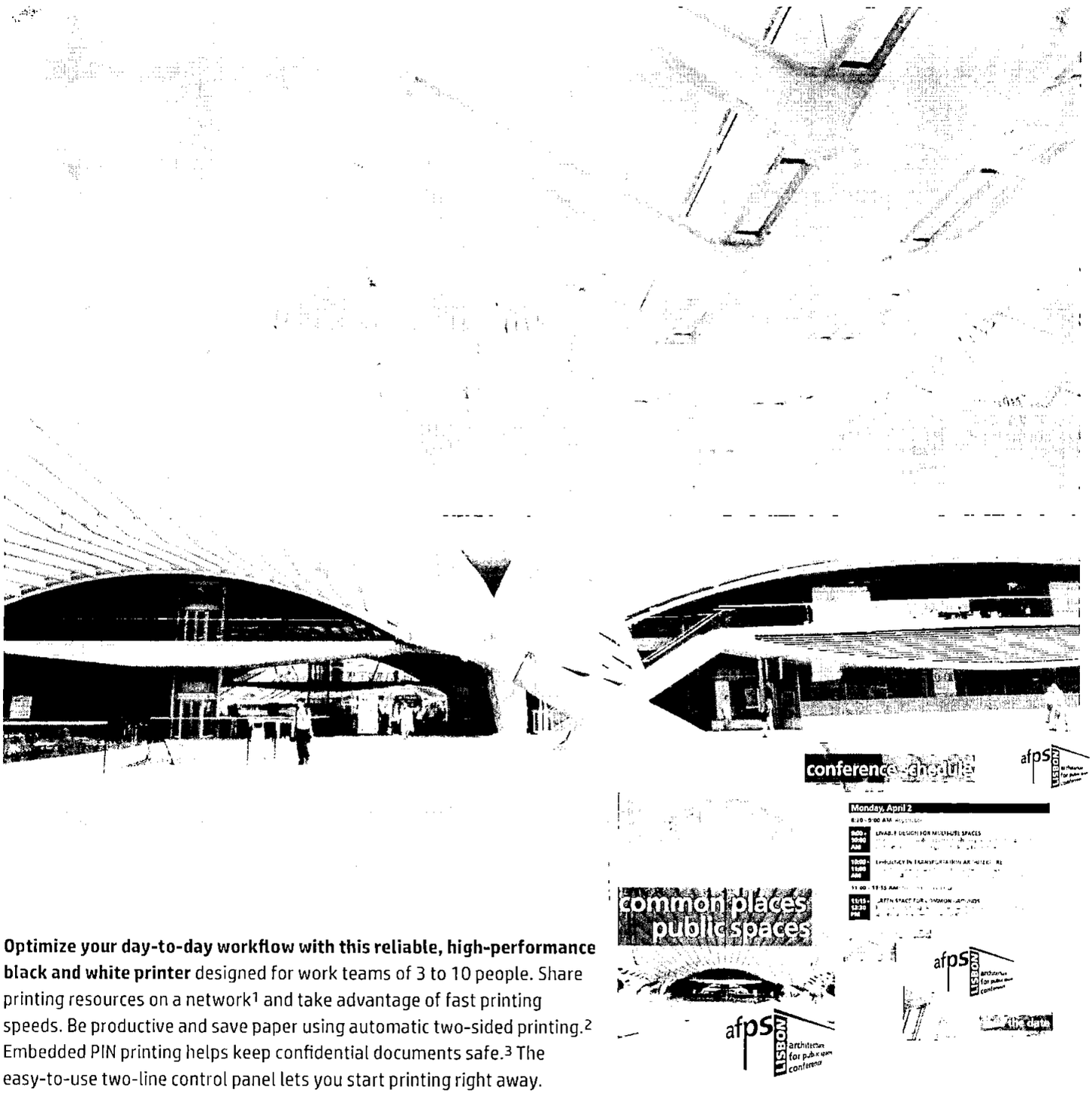

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ATTESTED

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

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MEMORANDUM OF UNDERSTANDING (MoU)

Between

ICMR-NATIONAL INSTITUTE OF TRADITIONAL MEDICINE (INDIAN COUNCIL OF MEDICAL RESEARCH) BELAGAVI-590 010, KARNATAKA

and

KLE ACADEMY OF HIGHER EDUCATION & RESEARCH (KLE Deemed-to-be-University) BELAGAVI-590 010, KARNATAKA

ICMR-National Institute of Traditional Medicine Belagavi, one of the premier research centres of the Indian Council of Medical Research (ICMR), a society established under the Societies Registration Act, 1860, an autonomous body under and fully funded by the Department of Health Research, Ministry of Health and Family Welfare, Govt of India, having its research facility at Nehru Nagar, Belagavi, and its head/registered office at V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110 029 (hereinafter referred to '**ICMR-NITM**' as the context permits).

KLE Academy of Higher Education and Research, Deemed-to-be-University Belagavi, Karnataka, a Deemed University, established u/s 3 of the UGC Act, having its office at Belagavi, Karnataka (hereinafter referred to as '**KAHER**' as the context permits). The KLE Deemed University has been accredited placed in '**A**' **Category** by the Government of India (Ministry of Human Resource Development) and has also been accredited with '**A**' **Grade** by National Assessment and Accreditation Council (NAAC).

Indian Council of Medical Research (ICMR) established in 1911, is an apex body in India for the formulation, co-ordination and promotion of biomedical research. The Council is engaged in conducting and promoting research in various areas of bio-medical science through its 31 permanent institutes/centres and through Headquarters using task force approach as well as providing financial assistance to *adhoc* research studies submitted by individual scientists from different parts of the country. The Council's priorities coincide with National Health Policies such as control and management of communicable diseases, fertility control, maternal and child health, nutrition and research on major non-communicable diseases like cancer, cardiovascular diseases, diabetes and other metabolic and hematological disorders, mental health research and drug research (including traditional remedies).

KLE Academy of Higher Education & Research (KLE Deemed University), Belagavi, Karnataka has been established u/s 3 of the UGC Act, 1956 vide Government of India, Ministry of Human

ATTESTED

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

MEMORANDUM OF UNDERSTANDING BETWEEN

OLARIS, INC

35 GATEHOUSE DRIVE, WALTHAM MA 02451 UNITED STATES OF AMERICA

AND

KLE ACADEMY OF HIGHER EDUCATION & RESEARCH

having its registered office at JNMC Campus, Nehru Nagar, Belgaum, Karnataka 590010, India (hereinafter referred to as "**KAHER**")

ON

IDENTIFYING "BIOMARKERS OF RESPONSE" (BOR) FOR ENDOCRINE THERAPY (ET) FOR INDIAN METASTATIC BREAST CANCER PATIENTS

This Memorandum of Understanding (MOU) is made between KLE Academy of Higher Education & Research (hereinafter referred to as "KAHER" located in Belagavi, Karnataka India and **OLARIS, INC** (hereinafter referred to as "Olaris"), a Delaware corporation in the United States of America, each wishing to establish a cooperative research relationship through mutual interests in the areas of identifying "biomarkers of response" (BoR) for endocrine therapy (ET) for Indian metastatic breast cancer patients.

KAHER and Olaris will hereinafter be referred to collectively as "Participants" or individually as "Participant", as applicable.)

WHEREAS KAHER and Olaris are linked by common scientific interest in identifying "biomarkers of response" (BoR) for endocrine therapy (ET) for Indian metastatic breast cancer patients;

WHEREAS KAHER and Olaris wish to enable cooperation and exchange in the research area of identifying "biomarkers of response" (BoR) for endocrine therapy (ET) for Indian metastatic breast cancer patients; and

ATTESTED

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

WHEREAS KAHER and Olaris wish to expand the basis for friendship and educational exchange between India and the United States of America;

NOW THEREFORE KAHER and Olaris, as Participants to this Memorandum of Understanding, set forth the following:

ARTICLE I (Background & Objectives)

1.1 ***WHEREAS*** KAHER is a Deemed to be University established u/s 3 of the UGC Act 1956. KAHER is committed towards international standards of health education and quality health care.

1.2 ***Objectives.*** This MOU reflects the Participants' sincere and genuine intentions to collaborate in specific activities set out herein pertaining to the research and development of identifying "biomarkers of response" (BoR) for endocrine therapy (ET) for Indian metastatic breast cancer patients. The purpose of this MOU is to advance the collaborative ideas and objectives of the Participants as they relate to this research, and enable each of the Participants to pursue the research activities and tasks set out in Article II of this MOU.

ARTICLE II (Scope of Collaboration)

2.1 ***General Scope.*** Each Participant will foster a collaborative research relationship with the other Participant that is focused on identifying "biomarkers of response" (BoR) for endocrine therapy (ET) for Indian metastatic breast cancer patients.

2.2 ***Specific Research Activities.*** The Participants intend to collaboratively pursue the following research activities and goals:

1. 2.2.1 KAHER will collect, store and ship plasma and clinical outcome data from metastatic Indian breast cancer patients at time of diagnose, 2 months post treatment and at time of regression over a period of 2-3 years.
2. 2.2.2 Olaris will perform metabolite profiling and machine learning analysis to determine if signatures exist that correlate with clinical outcomes.
3. 2.2.3 Olaris will determine if a BoR exists that predicts ET efficicacy for Indian metastatic breast cancer patients

2.3 ***Further Agreements.*** It is envisioned that the Participants will enter into further binding agreements involving or related to the collaborative research activities in Article 2.2 above ("Further Agreements"). Further Agreements will delineate the Participants' rights and obligations, will address, among other things, sources of funding and intellectual property rights, and be signed by

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

both Participants' authorized signatories, before commencing any research activity.

2.3.1 Each Participant's Liaison Officer, as designated in Article 4.6 below, will coordinate with its Office of Research, or equivalent, regarding any Further Agreements identified and proposed under this MOU prior to initiating projects or applying jointly for external funding for such projects.

2.3.3 Each Participant will abide by all regulations, policies and procedures of their Institutions regarding the disclosing and handling of intellectual property, developed technologies, and confidential information that may arise under this MOU.

2.4 ***Tasks for Participants.*** Each Participant will maintain regular and reasonable contact with the other Participant and engage in discussions regarding collaboration and the research activities listed herein. Further, each Participant will nominate members of its senior staff to be responsible for overseeing matters pertaining to this MOU.

2.5 ***Funding.*** Specific funding allocations for the exchange of faculty, staff, and graduate student researchers ("Participating Researchers"), shall be subject to the approval of the individual Participant and are not binding as a result of this MOU. Except as may be stipulated in any specific subsequent agreement, each Participant shall be responsible for expenses incurred by its employees under this MOU. It is expected the KAHER will cover all costs associated with patient sample collection and Olaris will cover all costs associated with sample analysis including cost of shipping.

ARTICLE III
(Duration, Termination and Amendment)

3.1 ***Duration.*** This MOU shall remain in force for four (4) years from the date of the last signature. Either Participant may terminate this MOU by providing 60 days' advance written notice to the other Participant. If the MOU is terminated, Participants agree to make efforts in good faith to develop a plan to finish any unaccomplished works. Failure to provide adequate notice is considered breach of contract and the at fault Party is subject to pay damages, which could include covering research costs.

3.2 ***Extension and Renewal.*** The Participants may extend this MOU by agreement, confirmed in a written amendment signed by each Participant's authorized signatory.

3.3 ***Amendment.*** No amendment of the terms of this MOU will be effective unless made in writing and signed by each Participant's authorized signatory.

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

ARTICLE IV (General Matters)

4.1 *Use of Names.* Except in promoting the activities proposed in Article 1.2 above among its faculty, staff, and students, neither Participant may use the name of the other Participant in any form of advertising or publicity without express written permission. The Participants will seek permission from one another by submitting the proposed use, well in advance of any deadline, to the Liaison Officers designated in Article 4.6 below.

4.2 *Confidentiality.* In the course of the activities under this MOU it may be necessary for the Participants to disclose Confidential Information. Unless otherwise expressly permitted in this agreement, any and all information, correspondence, financial statements, records, data, or information that is competitively sensitive and not generally known to the public, including formulations, analysis, inventions, improvements and activities of the disclosing Participant, disclosed by one Participant to the other Participant of this MOU, and other documents transmitted or communicated by either Participant to the other Participant that is marked as confidential or proprietary for the purposes of this agreement ("Confidential Information") shall be received and treated in confidence, and shall not be used by the receiving Participant or disclosed by the receiving Participant without the prior written consent of the disclosing Participant, which consent shall not be unreasonably withheld or delayed. These restrictions on use or disclosure of information do not extend to any item of information which (a) is publically known at the time of the disclosure, (b) is lawfully received by the receiving Participant from a third party which does not have a confidential relationship to the disclosing Participant, (c) the receiving Participant can demonstrate was in its possession or known by it before its receipt from the disclosing Participant, or (d) the receiving Participant is required by law to disclose to government authorities (including courts). Unless otherwise required under a subsequent binding agreement, each receiving Participant shall, at the expiry or termination of this agreement, return to the disclosing Participant any and all documents provided by the disclosing Participant setting out as Confidential Information.

4.3 *Potential for Intellectual Property Development.* It is understood that activities contemplated under this MOU are expected to be cooperative in nature and that Participating Researchers (including students, faculty, and staff researchers) may collaborate in such research activities.

4.3.1 "Intellectual Property" or "IP" means all patentable discoveries, innovations, inventions, improvements, devices, equipment, and designs, conceived and reduced to practice under the term of and in performance of this agreement.

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

4.3.2 Participants hereby agree that ownership of intellectual property rights generated as a result of the activities under this agreement will be solely owned by Olaris. Each Participant to this MOU shall own the intellectual property (IP) conceived and first reduced to practice solely by its employees or agents in furtherance of projects or activities contemplated by this agreement.

4.3.3 All copyrights, patents, trademarks, trade secrets, and any other intellectual property rights ("IPR") disclosed in connection with this MOU shall remain the property of the Participant introducing and/or disclosing the same to the other Participant for the purposes of this MOU.

4.4 *Export Control.* It is recognized and understood that this MOU is subject to all applicable export control laws and regulations controlling the transfer of technical information or items out of the respective countries of the Participants. The transfer of certain technical information or items may require a license from the respective governments of the Participants. Participants to this MOU must comply with all applicable export control laws and regulations and no Participant may export or allow the export or re-export of any information or item when to do so would constitute a violation of those laws or regulations.

4.5 *Human and Animal Subjects in Research.* Participants agree that adequate safeguards shall be taken whenever using human or animal subjects in research, consistent with applicable laws and policies regarding the use of human and animal subjects, including training of such trainees, faculty, or staff, an institutional review committee, research ethics board, or animal care and use committee composed of members with varying backgrounds who will perform complete and adequate review of projects involving the use of such subjects. Informed consent shall be obtained in accordance with national laws and regulations, international research standards, and accepted guidelines on good research practices and ethics. Each Participant shall, to the extent necessary for the legal conduct of activities under this MOU, comply with the laws and regulations of the other Participant's country.

4.6 *Notices.* The Participants must give all notices under this MOU in writing. All communications must be sent to the addresses set forth below or to such other address designated by the Participants by written notice. Notices are effective upon receipt.

For Olaris:

Elizabeth O'Day, MPhil, PhD

CEO/Founder

Olaris, Inc

ATTESTED

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

35 GATEHOUSE DR.

WALTHAM, MA 02451

Tel: 617-962-1634
Email: eoday@olarisBoR.com

FOR KAHER

KLE Academy of Higher Education & Research,
JNMC Campus, Nehru Nagar,
Belagavi 590010, Karnataka, India

4.7 Indemnification.

4.7.1. Olaris agrees to defend, indemnify and hold KAHER, its officers, employees and agents harmless from and against any and all liability, loss, expense, attorneys' fees, or claims for injury or damages arising out of the activities under this MOU, but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of Olaris.

4.7.2 KAHER agrees to defend, indemnify and hold Olaris, its officers, employees and agents harmless from and against any and all liability, loss, expense, attorneys' fees, or claims for injury or damages arising out of the activities under this MOU but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of KAHER

4.8 Dispute Resolution. The Participant's agree to make efforts in good faith to resolve all disputes amicably and expeditiously between themselves. Any dispute related to this contract that cannot be resolved shall be finally settled by binding arbitration conducted expeditiously in accordance with the J.A.M.S./Endispute Comprehensive Arbitration Rules and Procedures (the "J.A.M.S. Rules"). The arbitration shall be governed by the United States Arbitration Act, 9 U.S.C. Sections 1 - 16, and judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The place of arbitration shall be Boston, Massachusetts.

4.9 Non-Binding Nature. This MOU is not intended to and does not give any person who is not a Participant to it any rights to enforce any of its provisions. Nothing in this MOU will be construed as creating a binding legal relationship between the Participants, with the exception of only Article IV herein which will

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

survive the expiry or termination of this MOU. This MOU is a broad statement of intent which sets forth the general basis upon which the Participants wish to proceed. No legal liability will arise in respect of any subject matter hereof unless a subsequent binding agreement is negotiated, approved, executed and delivered by the Participants to this MOU.

4.10 Authorized Signatories. Each Participant represents that the individuals signing this MOU have the authority to sign on its behalf in the capacity indicated.

Signed for and on behalf of:

KLE Academy of Higher Education & Research

By: Dr (Prof) V.D. Patil

Registrar

Date; 10/7/2019

Signed for and on behalf of:

OLARIS, INC

By:

Elizabeth O'Day, MPhil, PhD
CEO/Founder

Date: 10/7/2019

ATTESTED

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

ATTESTED

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

Agenda

Signing of Memorandum of Understanding between

KLE Dr M.S.Sheshgiri College of Engg and Tech, Belagavi

and

KLE Vishwanath Katti Institute of Dental Science, Belagavi

Monday, 6th July, 2020 at 11am

Venue: Vision Conference Hall, KLE Dr MSSCET, Belagavi

1 Welcoming the audience – Dr Umesh Deshannavar, Dean (Affiliation & SEP)

2 Floral welcome to Dr Alka Kale by Dr Basavaraj Katageri

3 Floral Welcome to Dr Basavaraj Katageri by Dr S. F. Patil, Dean (Student Welfare)

3 Department Facilities– Dr C.V.Adake, HOD, Mech Engg, KLE Dr MSSCET

4 About the MoU – Dr Anand Patil, HOD, Dept of Prostho, KLE VK IDS

5 Remarks by Dr Alka Kale, Principal, KLE VK IDS

6 Remarks by Dr Basavaraj Katageri, Principal, KLE MSSCET

7 Signing of MoU

8 Closing remarks: Dr M. A. Kamoji, Dean (Academic)

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

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Description of Document	:	Article 12 Bond
Description	:	MOU
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Second Party	:	PRINCIPAL KLE DR MSS CET BELAGAVI
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MEMORANDUM OF UNDERSTANDING

This Memorandum of understanding is entered into and executed on Monday, 6th of July, 2020 by and among:

BETWEEN

ATTESTED

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

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The Department of Prosthodontics of **KLE Vishwanath Katti Institute of Dental Sciences, Belagavi**, a constituent unit of KLE Academy of Higher Education & Research, (Deemed-to-be University) having its office at Department of Prosthodontics, KLE VK IDS, Nehru Nagar Belagavi - 590010, India represented by its Head of Department, Dr Anand G. Patil, herein / after to be referred to as **"KLE VK IDS"** which expression shall unless repugnant to context thereof, mean and include its successors and permitted to assign as the **First Party.**

AND

Department of Mechanical Engineering, **KLE Dr. M. S. Sheshgiri College of Engineering and Technology,** Udyambag Belagavi - 590008 represented by its Head of Department Dr. C. V. Adake herein / after referred to as **"KLE Dr MSSCET"** which expression shall unless repugnant to context thereof, mean and include its successors and permitted to assign as the **Second Party.**

This MoU is signed between the two Institutions for the mutual benefit of KLE VK IDS, Belagavi & KLE Dr MSSCET, Belagavi and a constituent institution of the KAHER in the following key areas and the same shall be valid for a period of five years from the date of signing this MoU for the following

1. Research Collaboration
2. Faculty Exchange
3. Joint Conference, Symposia and Workshops
4. Sharing of Knowledge Resources
5. State of art management of patients requiring Maxillofacial & Implant Prosthesis with 3D printing Technology.

It is hereby agreed between the two Institutions viz KLE VK IDS and KLE Dr MSSCET as under: -

1. Research Collaboration

Both the institutions shall work together and contribute in any specially identified Research works involving Department of Prosthodontics and execute the activities agreed upon in publications, reports, informational materials, messages or any other means used to disseminate information on these activities without any financial implications.

2. Faculty Exchange

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

The faculty members identified by KLE VK IDS shall be officially permitted to visit KLE Dr MSSCET to enable them to keep in touch with the specialty / specialties, update themselves with the knowledge & skill in this filed and also to undertake research work at either institution without any financial liabilities.

3. Joint Conference, Symposia and Workshops

Both the Institutions being centers of higher education for Post Graduation course and Ph.D, it is mutually agreed that they shall share the Organizing Committees of any specific Conference, Workshop or Symposia which shall be based on common topics like Oral rehabilitation through scanning 3D printing and addictive manufacturing technology.

4. Sharing of Knowledge Resources

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

5. Patient Care

The Department of Prosthodontics of KLE VK IDS, the state of art management of those patients who require specific treatment and those patients who agree for the same, like Maxillofacial & Implant Prosthesis with 3D printing Technology shall be included through this MoU.

It is hereby agreed that KLE Dr MSSCET shall permit the Post Graduate students / Research Scholars / Faculty members of KLE VK IDS to utilize services of 3D printing and additive manufacturing Technology. KLE Dr MSSCET shall provide necessary materials at subsidized concessional rates or even free of cost for the treatment of needful patients.

IMPLEMENTATION

a) All activities implemented under the terms of this MoU shall be mutually agreed upon in writing, including the necessary approval for the program of activity as the need may arise.

b) KLE Dr MSSCET shall be solely responsible logistically and financially for the activities including repair and maintenance carried out under its direction or by its staff, except as otherwise agreed by both the **Parties**.

c) Both the **Parties** will designate one scientific representative each who will develop and coordinate specific programs or activities between them.

ATTESTED

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

FINANCIAL IMPLICATION

This MoU is a non-financial MoU and does not involve funding as an obligation on both the **Parties.**

DURATION AND RENEWAL OF AGREEMENT

This MoU will become effective immediately after signature by the representatives of KLE VK IDS and KLE Dr MSSCET, Belagavi for a period of five years and is subject to revision or modification by mutual agreement.

AMENDMENTS

a) This Memorandum of Understanding may be amended by a written agreement signed by the representatives of both Institutions.

b) All the equipment will be designed to operate in safe conditions. Only authorized persons shall be allowed to operate the machines only after they are thoroughly trained by the 'Mechanical Engineering Department' for all its employees KLE Dr MSSCET is having General Insurance for all its employees. KLE Dr MSSCET shall ensure about the insurance for the equipment.

c) In the event of any unforeseen incident during collaborative activities in either Institution, both Institutions agree to negotiate a mutually acceptable solution.

d) Should any disagreement arise out of the application, interpretation or implementation of this Agreement, both the **Parties** shall endeavor to exercise best efforts to negotiate their differences.

TERMINATION OF AGREEMENT

At any time during its period of validity, this agreement may be terminated by either **Party** upon prior notice to the other in writing not later than three months before termination date, provided that such termination shall not affect the completion of any program or activity underway at the time the notice of termination is given.

APPROVAL

In witness whereof, the **Parties** have signed and executed the above MoU to be executed as on 06/07/2020 herein above mentioned in presence of the following witnesses:

ATTESTED

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

Authorized Signatory
Professor and Head
Department of Prosthodontics
KLE VK Institute of Dental Sciences,
KAHER, Nehru Nagar,
Belagavi - 590010.

Authorized Signatory
Associate Professor & Head
Department of Mechanical Engineering
KLE Dr M. S. Sheshgiri College of
Engineering & Technology, Udymabag
Belagavi - 590008.

For and on behalf of
KLE VK Institute of Dental Sciences

Authorized Signatory
Principal,
KLE VK Institute of Dental Sciences,
KAHER, Nehru Nagar,
Belagavi - 590 010.

Date: 06 JUL 2020
Seal:

PRINCIPAL
KLE V.K. Institute of Dental Sciences
Nehru Nagar, BELAGAVI-590010

For and on behalf of
KLE Dr. MSSCET

Authorized Signatory
Principal
KLE Dr M. S. Sheshgiri College of
Engineering & Technology
Belagavi – 590008

Date: 06 JUL 2020
Seal:

PRINCIPAL
KLE DR. M. S. Sheshgiri
College of Engg. & Tech
BELGAUM

Signature of Witness 1:

Professor,
Department of Prosthodontics
KLE VK Institute of Dental Sciences,
KAHER, Nehru Nagar,
Belagavi - 590 010.

Signature of Witness 3:

Professor & Dean (Academic)
Department of Mechanical Engineering
KLE Dr M. S. Sheshgiri College of
Engineering & Technology, Udymabag,
Belagavi- 590008

Signature of Witness 2:

Senior Lecturer
Department of Prosthodontics
KLE VK Institute of Dental Sciences,
KAHER, Nehru Nagar,
Belagavi - 590 010.

Signature of Witness 4:

Professor & Dean (Affiliations & SEP)
Department of Chemical Engineering
KLE Dr M. S. Sheshgiri College of
Engineering & Technology, Udyambag,
Belagavi - 590008

ATTESTED

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

Memorandum of understanding (MoU) Between

Government Ayurvedic Medical College and K.L.E College of Pharmacy

A. Parties

1.Government Ayurvedic Medical College,
Mahavantari Road,
Bangalore-560009,Karnataka,India
Ph: 080 22872848
Fax: 080-22872848

2.K.L.E College of Pharmacy
P B No 1062, 2nd block,Rajajinagar
Bangalore-560010,Karnatakastate,India
Ph: +91(0) 8023325611
Fax:+91(0) 8023425373

B. Government Ayurvedic Medical College,Bangalore

GAMC which has been awarded as,the Centre of excellence was established in 1967.The College is affliated to Rajiv Gandhi University of Health sciences,Bangalore.The college offers Under graduate,Post graduate and Ph.Dcources in Ayurveda.The SJIIM Hospital premises are within the campus.The 275 bededhospital,well equipped OPD with a daily attendece of around 250-300 patients and a vast herbal garden.The institute has comprehensive facilities for teaching ,inexhaustible resources for medical and allied research and provides credible patient care.

ATTESTED

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

C.K.L.E College of Pharmacy,Bangalore

K.L.E College of Pharmacy, P.B No 1062, 2nd block,Rajajinagar ,Bangalore-560010, is affiliated to KLE Academy of Higher Education and Research, Belagavi , which has more than 250 institutions under its ambit. K.L.E College of Pharmacy,Bangalore is approved by All India Council for Technical education(AICTE) and Pharmacy Council of India(PCI) offering B Pharm., M. Pharm., Pharm.D. and Ph.D. (Pharmaceutical Sciences) Programs. The college is accredited by NAAC and NBA. The Institution is located in the heart of the city with good infrastructure and research facilities under 4 departments namely, Pharmaceutics, Pharmacology, Pharmaceutical chemistry and Pharmacognosy. We are conducting consultancy projects for the industries,specially pre -clinical studies,

D. Areas of Collaboration

It is agreed that K.L.E College of Pharmacy, Bangalore and Government Ayurvedic Medical College, Bangalore will allow their respective Professors to collaborate in the above mentioned areas.Training and re- training of individuals/teams as per the need would be provided naturally.Experimental protocols will be discussed by the experts of both institutions and finalized to carry out necessary studies. it is also envisaged that the research carried out under this joint collaboration will lead to the acquisition of knowledge that will be helpful in the advancing research in the fields of pharmacy sciences and public health.

E. Confidentiality, soft and hard outputs

The work in part may involve on both sides some other customers/entrepreneurs and would require maintaining the required confidentially. Every publications/patents resulting out of this collaboration shall be approved by the heads of both institutions, viz, Principal, Government Ayurvedic Medical College and Principal, K.L.E College Of Pharmacy. The teams involved in the research are expected to maintain the records of the work to support publications/patenting. The team members involved in each project may be listed/updated and approved by both the heads.

G. Termination

Either party may request for termination of this MoU at any time by giving 3 months notice in writing. However ,Ongoing activities should be allowed to continue in accordance to the specifics outlined programme-wise.

ATTESTED

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

H. Amendments

Amendments are changes to this MoU.Shall be made in writing and signed by the duly authorized representatives of both parties.The terms and conditions of any specific programme between Government Ayurvedic Medical College and K.L.E College of Pharmacy will be discussed by both parties and set forth in a subsequent Agreement between the parties.

I.Effective Date

The Memorandum of Understanding shall become effective upon signature by the respective parties and shall remain in force until further notice.

Whereas , the undersigned do hereby agree to the terms set forth in this MoU.

For Government Ayurvedic Medical College

For K.L.E College of Pharmacy

PRINCIPAL
KLE UNIVERSITY'S
COLLEGE OF PHARMACY
Block, Rajajinagar, Bengaluru-10

Witness:

Dr. LALITHA B.R
MD(Ay), Ph.D.,
Professor & HOD
Dept of PG Studies in Dravyaguna
Govt. Ayurvedic Medical College
Bangalore-560 009

Witness:

Dr. PURNIMA ASHOK
Professor and Head
Department of Pharmacy Practice
KLE College of Pharmacy
Bengaluru-560 010

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

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Purchased by	:	REGISTRAR KAHER
Description of Document	:	Article 12 Bond
Description	:	M O U
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First Party	:	REGISTRAR KAHER
Second Party	:	PRINCIPAL KLE CET
Stamp Duty Paid By	:	REGISTRAR KAHER
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Shri Siddhivinayak Banjara MCSL.
C/o. K. T. Patil Building Chavat Galli, BGM

Authorised Signature

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This Memorandum of understanding is made and executed on this the 14th day of December 2020

...2

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

KLE COLLEGE OF ENGINEERING AND TECHNOLOGY

Chikkodi, Belagavi, Karnataka

The KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER) Belagavi, Karnataka, India and, KLE College of Engineering and Technology (KLECET), Chikkodi, Belagavi, Karnataka, 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

ATTESTED

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

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.

PREAMBLE of KLECET

The KLE Society's KLE college of Engineering and Technology has been established in the year 2008 with the sole objective of imparting quality technical education for rural youth. The college is located in the Taluka headquarters of Chikkodi or Belgaum District about 70 kms from Belgaum. The campus has a sprawling area of 16 acres at the foot of hillocks on the outskirts of the city.

The city of Chikkodi has a strong educational base and enjoys salubrious climate throughout the year. The institute is a self-financed non-minority college recognized by AICTE, New Delhi and Government of Karnataka.

ATTESTED

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

It is affiliated to Vishvesvarayya Technological University, Belagavi, the technical state University of Karnataka. The institute has state of the art infrastructure and most modern facilities

PURPOSE / OBJECTIVE

The Primary purpose of this MoU is for the **development of ongoing framework for student and staff joint projects to promote effective, safe, skillful & knowledgeable research 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 colleges 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.

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

1. Joint research projects
2. Co-author and collaborate in areas of research interest

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

3. Exchange of academic/research information and related materials to facilitate joint publications by collaborating faculty members
4. Promoting any related academic activities based on mutual agreement

Responsibilities of KAHER Institute of Nursing Sciences, Belagavi, Karnataka, India KLE College of Engineering and Technology (KLECET), Chikkodi, Belagavi, Karnataka will:

1. Arrange local logistics and local travel, during visits
2. Arrangement of food and accommodation within minimal cost if it requires
3. Providing technical inputs in all phases of MOU.
4. Providing hardware components cost of the project work.
5. Travel costs will not be provided to faculty and students.

TERMS OF AGREEMENT

Both colleges 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.

ATTESTED

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

ATTESTED

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

FDP Research Subaward Agreement
Amendment (Number 1)

Pass-Through Entity (PTE)		Subrecipient
Thomas Jefferson University	Entity Name	Jawaharlal Nehru Medical College, KLE
125 S 9th St, 2nd Floor Sheridan, Philadelphia, PA 19107	Email Address	sgoudar@jnmc.edu, bkilledar@jnmc.edu,
Richard Derman	Principal Investigator	Shivaprasad Goudar

Project Title: TJU-JNMC Global Network for Women's & Children's Health Research Unit

PTE Federal Award No:	Federal Awarding Agency:
2UG1HD076457-07	National Institutes of Health (NIH)

Subaward Period of Performance:	Amount Funded This Action:	Subaward No:
Start Date: Jun 1, 2019 End Date: May 31, 2020	$ 478,086.00	080-70000-S22902

Effective Date of Amendment:	Total Amount of Federal Funds Obligated to Date:	Subject to FFATA:	Automatic Carryover:
Jun 1, 2019	$ 478,086.00	(•) Yes ( ) No	( ) Yes (•) No

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Research Subaward Agreement as follows:

ACTION:

To authorize funding of $478,086 for the current budget period from June 1, 2019 to May 31, 2020.

If there are funds remaining from the prior budget period, a request for carryover may be submitted, along with the final invoice, within 60 days of end of the period of performance.

For clarity, all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
Timothy Schailey	10/16/19		Jul 16, 2019
Name: Timothy Schailey	Date	Name: Dr. (Mrs.) Niranjana S. Mahantashetti	Date
Title: Director, Office of Research Administration		Title: Principal	

FDP Bilateral Mod Sept.2017

ATTESTED

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

Notice of Award

Cooperative Agreement
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 06/13/2019

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5UG1HD076457-07
FAIN: UG1HD076457

Principal Investigator(s):
RICHARD J DERMAN, MD

Project Title: TJU-JNMC Global Network for Women's & Children's Health Research Unit

Margaret Burwell
Assistant to the Director
125 S. 9th Street
Philadelphia, PA 191075125

Award e-mailed to: resadmin@jefferson.edu

Period Of Performance:
Budget Period: 06/01/2019 – 05/31/2020
Project Period: 07/01/2013 – 05/31/2023

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $607,360 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THOMAS JEFFERSON UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UG1HD076457. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

ATTESTED

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

RTI INTERNATIONAL

FIXED AMOUNT AWARD AGREEMENT

Between

Research Triangle Institute (RTI)

And

KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI

Agreement Summary:

1. Agreement Number	
2. Type of Agreement	Fixed Amount Award
3. Agreement Activity Title	**To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital**
4. Agreement Administrator	**US Address:** Research Triangle Institute (RTI) 36040 Cornwallis Road - P. O. Box 12194 Research Triangle Park, NC 27709-2194 – USA
5. RTI Agreement Officer	
6. Recipient Organization	**KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI**
7. Recipient Organization's 's Point-of-Contact	Niranjana Mahantashetti principal@jnmc.edu **+918312471350**
8. Prime Award Number	**OPP-1180554**
9. Project Title	**MITS Surveillance Alliance**
10. RTI Project No	**0216178**
11. Period of Performance	**Start Date: July 1, 2019** **End Date: September 30, 2020**
12. Agreement Ceiling	**$80,000**
13. RTI Technical Monitor	**Norman Goco**
14. Incorporated Documents	**Attachments A-B**
ATTACHMENTS:	
Attachment A: Project Description	
Attachment B Standard Provisions	

ATTESTED

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

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RTI INTERNATIONAL

This Agreement is awarded to **KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI** (hereinafter called "Awardee") and administered by **Research Triangle Institute** (hereinafter called "RTI"), a not-for-profit corporation existing under the laws of the State of North Carolina, USA and having its principal place of business at 3040 Cornwallis Road, Research Triangle Park 27709-2194, under above mentioned award between Gates Foundation and RTI to support implementation of the **To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital**

(hereinafter called "Project").

Whereas:

A. This Grant will implement specific activities that will contribute to achievement of the overall Project Objectives.

B. This Agreement shall not (i) create the relationship of principal and agent, employer and employee, joint venture, or business partnership between RTI and the Awardee; and (ii) establish privity of contract between Gates Foundation and the Awardee.

C. Authority of Agent: Designated agents on behalf of the Awardee and RTI are the sole authority authorized to make amendments and any other substantive changes to the Agreement Terms.

Now, therefore, in consideration of the promises and of the mutual covenants and Agreements contained herein, and intending to be legally bound, RTI and the Awardee hereby agree to the following terms and conditions of this Agreement.

Article 1. PROGRAM DESCRIPTION

The purpose of this Agreement is to provide support for the activities described in the Program Description in **Attachment A** of this Agreement.

Article 2. PERIOD OF PERFORMANCE

The period of performance for the Agreement activities is July 1, 2019 to September 30, 2020.

All activities financed with Agreement funds will not commence prior to the Agreement Activity Start date, and will be completed and will cease no later than the Agreement Activity Completion Date; unless RTI provides approval of a time extension in writing prior to the specified Agreement Activity Completion Date. No award will provide for retroactive funding.

Article 3. CEILING AMOUNT OF AWARD AND BUDGET

RTI hereby awards the amount of $30,000 for the purposes of this Agreement. A potential increase of $50,000 is possible if acceptable progress is made, allowing for a ceiling of $80,000.

Payments will be made to the Awardee upon presentation to RTI a properly prepared invoice, with a certification that the Milestone being billed has been completed and providing any other documentation required by RTI specified for that Milestone in the chart below. An invoice format may be provided upon award of this Agreement. Each invoice shall include the following: Agreement Number, Milestone being billed and fixed amount associated with that Milestone.

On submission of the invoice for the final Milestone, the Awardee shall certify that the Agreement is completed and the Awardee will make no further claim against RTI after final payment.

ATTESTED

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

RTI INTERNATIONAL

Article 4. PAYMENT MILESTONES AND DISBURSEMENT SCHEDULE

The approved Payment Milestones and disbursement schedule:

Milestone	Description of Milestone	Required Deliverable	Completion Date (if applicable)	Amount (Local Currency or USD)
1	Organization IRB Approval of the program	IRB Approval Letter	TBD	25% of total award value - $7,500
2	Recipient organization staff trained*	Training certificate	TBD	25% of total award value -- 7,500
3	50% of MITS utilized	Documentation of MITS used and corresponding QC process complete	TBD	25% of total award value - $7,500
4	Program completion report	Program completion report	TBD	25% of total award value - $7,500
Total				$ 30,000

*The Awardee may proceed with training, however the second milestone for training completion cannot be paid until the first milestone for IRB approval is complete.

Article 5. PROGRAM REPORTING
Awardee

The Awardee will be responsive to requests for programmatic information and results by the Technical Monitor. RTI will conduct monitoring of the program activities, including site visits as appropriate.

Article 6. TITLE TO PROPERTY

Title to all property purchased under this Agreement shall be vested in the Awardee.

Article 7. RECORDKEEPING, RIGHT OF INSPECTION AND AUDIT

Right of inspection: RTI reserves the right to review all program related documentation, and any documents related to proper compliance during the implementation of the Agreement and up to a period of 3 years after the end-date of this Agreement. Therefore, Awardee agrees to maintain records funded by this Agreement for the period above.

The Awardee will commit to eliminate all the deficiencies or refund RTI for any unallowable costs found in resulting Inspection Report within 60 days.

ATTESTED

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

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RTI INTERNATIONAL

Article 8. TERMINATION AND SUSPENSION

This Agreement may be terminated by RTI at a date earlier than the proposed end-date under the following conditions:

1) Significant change in the scope of work: If the requirements of the donor or the program change such that the work to be completed varies significantly from the proposed activities.

2) Reduction or termination of donor funding.

3) As a requirement of the donor: In the event the donor requests early termination of the Agreement.

4) Significant delays or external or internal challenges which have a material impact on the ability of the Awardee to implement the activities.

The Awardee will be notified in writing of proposed termination or suspension and outline close out procedures of the Agreement.

Article 10. LIABILITY

RTI does not assume liability for any third-party claims for damages arising out of this Agreement.

Article 11. DISPUTES

Any dispute under or relating to this Agreement shall be decided by the RTI Agreement Officer.

Article 12. SPECIAL PROVISIONS

The Awardee should comply with the Standard Provisions contained in Attachment B.

IN WITNESS OF THEIR AGREEMENT and their acceptance of its terms and conditions, RTI and the Awardee hereby execute this Agreement.

RTI International	**KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI**
Signature: Digitally signed by Tim Fetner	**Signature:**
Name: Tim Fetner	**Name:** Dr. N.S. Mahantashetti
Title: Sr. Strategic Sourcing Officer	**Title:** Principal, J.N. Medical College.
Date: July 2, 2019	**Date:** July 17, 2019

ATTESTED

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

RTI INTERNATIONAL

ATTACHMENT B

STANDARD PROVISIONS

GLOBAL ACCESS TO INTELLECTUAL PROPERTY

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

LICENSE TO RTI-

For the purpose of achieving Global Access, You grant the RTI a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to: make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the Funded Developments and any Background Technology incorporated into a Funded Development or required to use a Funded Development. In the event You demonstrate to the satisfaction of RTI that Global Access can best be achieved without such a license (or a license of different scope) RTI and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION

Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by RTI, You will seek prompt Publication of any Funded Developments consisting of data and results. "*Publication*" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by RTI in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, such Publication shall be under "open access" terms and conditions consistent with RTI's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

PUBLICITY

PUBLICITY BY YOU

You must obtain the RTI's prior written approval before: (a) issuing a press release or other public announcement regarding this grant; and (b) any other public use of the Gates Foundation's name or logo. Please email Your request to the Technical Monitor. Detailed guidelines are available at:

www.gatesfoundation.org/grantseeker/documents/guidelines_communications_for_grantees.doc.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

ATTESTED

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

RTI INTERNATIONAL

You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, (North) Sudan, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by RTI in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to RTI or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

LOBBYING AND ELECTIONEERING PROHIBITION
You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You acknowledge that RTI has not earmarked Grant Funds to support lobbying activities or to otherwise support attempts to influence legislation. Activities will be conducted consistent with the private foundation lobbying rules and exceptions under Internal Revenue Code Section 4945 and related regulations. You confirm that the Budget (or the combined project budget if there are multiple funders) accurately reflects that You will expend at least the amount of the Grant Funds on (a) non-lobbying activities in the project year, or (b) for multiple year projects, the total non-lobbying portion of the project.

OTHER LOBBYING, GIFT, AND ETHICS RULES
You agree to comply with any national, state, local, or other lobbying, gift, and ethics rules applicable to the Project. RTI is not retaining or employing You to engage in lobbying activities.

ATTESTED

Prof. Dr. V.A.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 Registration	2019/933680-0
Purchase Order	202328665
Unit Reference	

Shivaprasad Goudar
(sgoudar@jnmc.edu)/gshivaprasad@hotmail.com
KLE UNIVERSITY
BELGAUM
KLE UNIVERSITY BELAGAVI
BELGAUM
KARNATAKA
590010
India

AGREEMENT FOR PERFORMANCE OF WORK (APW)

Re: The aim of this APW is to conduct an evaluation of the WHO Labour Care Guide in two facilities in India.

We are enclosing the Agreement for Performance of Work between the World Health Organization and KLE UNIVERSITY, BELGAUM, in the amount of INR 1,393,418.18 (One Million Three Hundred Ninety-Three Thousand Four Hundred Eighteen And 18/100), for conducting the above-mentioned work. We also enclosed two 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 questions relating to this Agreement, please contact the responsible technical officer, Mercedes BONET SEMENAS, bonetm@who.int.

Invoicing Instructions for Contractors who are legal entities (Company Contractors):
Invoices must be sent via email to accountspayable@who.int. Other than invoices, please do not send any enquiry to this email address. You may contact the above responsible technical officer for enquiries.

In order to ensure timely and accurate payment, invoices must include:

- Invoice number
- Purchase Order number against each invoice line;
- Invoice descriptions matching with PO descriptions
- Invoice currency same as the Purchase Order Currency also corresponding with the currency of the bank account provided to WHO;
- Supplier name as in the PO

Invoices shall be clearly readable and stamps or any other additional markings should not obscure the original invoice content. Invoices shall not be handwritten.

On behalf of the World Health Organization, we would like to thank you for your collaboration.

WHO Global Service Centre

cc: WHO India

Concerne: The aim of this APW is to conduct an evaluation of the WHO Labour Care Guide in two facilities in India.

Veuillez trouver ci-joint l' Accord pour Exécution de Travaux entre l'Organisation Mondiale de la Santé et KLE UNIVERSITY, BELGAUM, pour un montant de INR 1,393,418.18, vous permettant de mener à bien le travail susmentionné. Veuillez également trouver 2 pièce(s) jointe(s) mentionnée(s) 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 (

9/8/2019

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

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2019/933680-0
Purchase Order	202328665
Unit Reference	

complet)

Pour toutes questions à caractère technique ayant trait à cet Accord, veuillez contacter le responsible Mercedes BONET SEMENAS, bonetm@who.int.

Instructions concernant la facturation pour les contractants qui sont des personnes morales.(Personne Morale):
Les factures doivent être envoyées par courriel à accountspayable@who.int Outre les factures, n'envoyez aucune enquête à cette adresse de courrier électronique.Vous pouvez contacter le responsable technique responsable ci-dessus pour toute demande de renseignements.

De manière à garantir un paiement exact et ponctuel, les factures doivent impérativement comporter:

- Le Numéro de facture
- Le Numéro du bon de commande , répété à chaque ligne de facturation
- Des descriptifs des produits identiques à ceux du Bon de commande
- Une devise de facturation identique à celle du Bon de commande et à celle du compte en banque fourni à l'OMS
- Un intitulé de facture (nom de fournisseur) identique à celui du Bon de commande.

Les factures doivent être parfaitement lisibles. Le contenu de la facture ne doit en aucun cas être masqué par un tampon ou tout autre marquage. La facture ne doit pas être manuscrite.

Au nom de l'Organisation mondiale de la Santé, nous vous remercions de votre collaboration.

Centre mondial de services de l'OMS

cc: OMS India

9/8/2019

ATTESTED

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

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World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
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MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2019/933680-0
Purchase Order	202328665
Unit Reference	

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
KLE UNIVERSITY
BELGAUM

BELGAUM
INDIA

The Fixed amount of/*Un montant Fixe de*: INR 1,393,418.18 (One Million Three Hundred Ninety-Three Thousand Four Hundred Eighteen And 18/100) **in respect of/*en vue de*:** The aim of this APW is to conduct an evaluation of the WHO Labour Care Guide in two facilities in India.

For the period financed by this Agreement — From/*De*: 20-JUL-2019
***Période du projet** financée par le présent Accord* — To/*A*: 15-NOV-2019

Summary of work/ *Description sommaire des travaux:*

Description of work under this Agreement/ *Description des travaux faisant l'objet du présent Accord:*

1. Co-ordinate training workshops (1 per facility) for participating providers (around 10 per facility) using standardized training materials (Providers to complete questionnaires after initial training)
2. Support participating providers to pilot-test the LCG in two facilities (target of 100 women per facility) and complete postpartum questionnaires after each case.
3. Co-ordinate focus group discussions (1 per facility), including transcription and translation (if required) and collect endline questionnaires from participating providers
4. Enter questionnaire data into online database
5. Attend multi-country project team calls and respond to requests for technical input as required

Financial arrangements/ *Dispositions financières:*

Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due date/ *Date remise*	%	Currency amount/ *Montant en devise*
1	On receipt of counter-signed contract	26-JUL-2019	0.00	0.00
2	On submission of deliverable 1 (local approvals)	30-AUG-2019	50.00	696,709.09
3	On submission of interim report on training worskhops (deliverable 2)	30-SEP-2019	30.00	418,025.45
4	On submission of final report, including deliverables 2 to 5	15-NOV-2019	20.00	278,683.64

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de l'Accord:*

Annex/Annexes	File Name/ *Nom du fichier*
1	2019/933680 | Contractual - Budget Breakdown |
2	2019/933680 | Contractual - Terms of Reference |

9/8/2019

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

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World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

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WHO Reference/ *Référence OMS*

WHO Registration	2019/933680-0
Purchase Order	202328665
Unit Reference	

In the event that 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 dispositions des annexes et celles de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.*

The undersigned parties, having read the terms and General Conditions, hereby conclude the present Agreement and confirm their agreement and acceptance thereof.
ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Mercedes Bonet Semenas
Medical Officer
HQ/RHR - Reproductive Health and Research

Approved by:
Approuvé par:

Olufemi Taiwo OLADAPO
Medical Officer
HQ/RHR - Reproductive Health and Research

Authorized Signatory:
Signataire autorisé:

Mr Richard Preston
Director (ai)
Global Service Centre
(WHO/GMG/GSC)

Processed by:
Traité par:

Katerina Gnanapragasam
Senior Procurement Assistant
HQ/GSC Global Service Centre
19-JUL-2019

Les parties soussignées, ayant lu les modalités et les Conditions Générales, ratifient l'Accord et confirment leur acceptation.

CONTRACTOR/ CONTRACTANT

Signature : .....

Date: 09/08/2019

Name & Title/ Nom & Fonction : Dr. N. S. Mahantashetti
Principal
JNMC, BELAGAVI

KAHER * BELAGAVI * J.N. MEDICAL COLLEGE

9/8/2019
Principal Investigator
JNMC Women's and Children's
Health Research Unit,
KAHER, J.N. Medical College,
BELAGAVI - 590 010.

ATTESTED

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

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World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
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63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

GENERAL CONDITIONS

1. Relationship of the Parties. It is understood that the execution of the work does not create any employer/employee relationship. In this respect, the contractor shall be solely responsible for the manner in which the work is carried out. Thus, WHO shall not be responsible for any loss, accident, damage or injury suffered by any person whatsoever arising in or out of the execution of this work, including travel. Insurance coverage for any such loss, accident, damage or injury will be the contractor's responsibility, including where appropriate, insurance coverage for persons used by the contractor to carry out the work.

Without prejudice to the foregoing, WHO may in certain cases provide insurance coverage for the contractor for travel in WHO vehicles. WHO declines all responsibility for non-payment by the insurance company of all or part of a claim submitted by or for the contractor for any accident. In case of such non-payment, the contractor shall be obliged to immediately reimburse all or part of any advance which WHO may have paid to the contractor.

2. Rights. All rights in the work, including ownership of the original work and copyright thereof, shall be vested in WHO, which reserves the right (a) to revise the work, (b) to use the work in a different way from that originally envisaged, or (c) not to publish or use the work.

3. Payment and use of funds. If the option, on the face of this agreement, for payment of a fixed sum applies, that sum is payable in the manner provided, subject to proper performance of the work.
If the option for payment of a maximum amount applies,
(i) the funds shall be used exclusively for the work specified in this agreement and any unspent balance shall be refunded to WHO. In this latter case, any financial statement required shall reflect expenditures according to the relevant main categories of expenditure, and
(ii) to the extent the contractor is required to purchase any goods and/or services in connection with its performance of this agreement, the contractor 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.

Contractors who are legal entities (hereinafter referred to as "Company Contractors") must submit an invoice to the contracting WHO department or the WHO Global Service Center in order to receive payment. Invoices are not required from contractors who are individuals (hereinafter referred to as "Individual Contractors"), who can be paid upon receipt by the contracting WHO department of the required deliverables (including any required technical reports and financial statements) in a satisfactory manner.

The invoice from Company Contractors shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Company Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this agreement and the work performed hereunder. As regards excise duties and other taxes imposed on the provision of goods and services (e.g. value added tax), the Company Contractor agrees to verify in consultation with WHO whether in the country where the tax would be payable, WHO is exempt from such tax at the source, or entitled to claim reimbursement thereof. If WHO is exempt from value added tax, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Company Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

WHO shall have no responsibility whatsoever for any taxes, duties or other contributions payable by contractors. Payment of any taxes, duties and other contributions which a contractor may be required to pay shall be the sole responsibility of that contractor who shall not be entitled to any reimbursement thereof by WHO.

4. Satisfactory performance. If the work is not satisfactorily completed (and, where applicable, delivered) by the date fixed in this agreement and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may specify an additional period within which this agreement must be satisfactorily performed. Normally such additional period should be of at least one week's

CONDITIONS GENERALES

1. Relation entre les Parties. Il n'est pas institué de relations d'employeur à employé aux fins de l'exécution des travaux. À cet égard, le contractant est seul responsable de la manière dont les travaux sont exécutés. Ainsi, l'OMS ne saurait assumer, à l'égard de quelque personne que ce soit, aucune responsabilité pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux ou d'un déplacement les concernant. La mise en place d'une couverture d'assurance pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux sera de la responsabilité du contractant y compris le cas échéant, toute couverture d'assurance pour les personnes auxquelles le contractant recourt pour l'exécution des travaux.

Sans préjudice de ce qui précède, l'OMS peut dans certains cas, fournir une couverture d' assurance au contractant en cas de déplacement dans un véhicule de l 'OMS. L'OMS décline toute responsabilité pour le non-paiement par la compagnie d'assurance de la totalité ou d'une partie d'une demande d'indemnisation soumise par ou pour le contractant suite à un accident. En cas de non-paiement, le contractant sera obligé d' immédiatement rembourser la totalité ou une partie des avances que l'OMS pourrait lui avoir versées.

2. Droits. Tous les droits attachés aux travaux, y compris la propriété des travaux originaux et le droit d'auteur y afférent, seront dévolus à l'OMS qui se réserve le droit a) de réviser les travaux, b) d'utiliser les travaux d'une autre manière que celle initialement envisagée ou c) de ne pas publier ni utiliser les travaux.

3 Paiement et utilisation des fonds Si l'option applicable - prévue au recto du présent accord - est celle du paiement d'une somme fixe, cette somme est payable dans les conditions prévues, sous réserve de l'exécution satisfaisante des travaux.
Si l'option applicable est celle du paiement d'un montant maximum :
(i) les fonds seront utilisés exclusivement aux fins des travaux précisés dans l'accord et tout solde non utilisé sera remboursé à l'OMS. Dans ce dernier cas, les états financiers requis devront indiquer les montants engagés pour les principaux postes de dépense , et
(ii) dans la mesure où le contractant doit acheter des biens et/ou des services quelconques dans le cadre de l'exécution du présent accord, il 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.

Afin d'être payé, les contractants qui sont des personnes morales (ci-après dénommés « Personnes Morales ») doivent présenter une facture au département contractant de l'OMS ou au centre mondial de services de l'OMS. Les contractants qui sont des personnes physiques (ci-après dénommés « Personnes Physiques ») ne sont pas tenus de présenter de facture et peuvent être payés au moment de la réception, sous une forme satisfaisante, des livrables requis (y compris tout rapport technique et état financier requis) par le département contractant de l'OMS.

La facture des Personnes Morales devra refléter toute exonération d'impôt à laquelle l'OMS pourrait avoir droit en vertu de l'immunité dont elle jouit. De manière générale, l'OMS est exonérée de tout impôt direct, de tout droit de douane et de tous droits et taxes similaires, et la Personne Morale devra se mettre en rapport avec l'OMS afin d'éviter l'application des dites charges en rapport avec le présent accord et les travaux qui en résultent. En ce qui concerne les impôts et autres charges indirects imposés sur la fourniture de biens et de services, (par ex: taxe à la valeur ajoutée), la Personne Morale accepte de vérifier en consultation avec l'OMS si, dans le pays où la charge serait exigible, l'OMS est exonérée de ladite charge à la source ou est en droit d'en réclamer le remboursement. Si l'OMS est exonérée de la taxe à la valeur ajoutée, cela devra être indiqué sur la facture, tandis que si l'OMS est en droit d'en réclamer le remboursement, la Personne Morale accepte de mentionner cette charge de façon séparée sur ses factures et, si nécessaire, de coopérer avec l'OMS afin d'en obtenir le remboursement.

L'OMS n'encourra aucune responsabilité pour quelque taxe, droit ou autre contribution dû par les contractants. Le paiement de quelque taxe, droit ou autre contribution qu'un contractant pourrait être tenu de payer sera de l'entière responsabilité de celui-ci et il n'aura droit à aucun remboursement de la part de l'OMS à ce titre.

4. Exécution satisfaisante. Si les travaux ne sont pas accomplis correctement (et, le cas échéant, fournis) à la date prévue par l'accord ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'OMS peut accorder un délai supplémentaire à l'expiration duquel l'accord doit être exécuté de façon satisfaisante. En règle générale, ce délai supplémentaire est d'une semaine au moins, à moins

9/8/2019

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WHO Reference/ *Référence OMS*

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

duration, unless it is clear from the agreement that it was particularly important that the performance be completed on the date specified, in which case WHO may specify a shorter period or refuse to grant any additional period at all. In the event that the work is not satisfactorily completed and delivered on the date fixed, or any additional period granted by WHO and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may immediately terminate this agreement (in addition to the other remedies), in accordance with general condition 13 below (without being held to grant the contractor an additional period of thirty (30) days to perform, complete and deliver the work).

5. Completion and delivery. The contractor shall complete and deliver the work to WHO (including any technical report that may be required) by the date fixed in this agreement or any additional period that may be granted by WHO under general condition 4 above. Any financial statement required shall be submitted within thirty (30) days thereafter at the latest. If the payment schedule on the face of this agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this agreement, including any technical report and financial statement.

6. Certification of status of individual contractors. Each Individual Contractor certifies that he/she does not presently, and will not during the term of this agreement, hold any form of contractual relationship with WHO (including any WHO regional, country or project office, as well as any programme, center or other entity where staff is subject to WHO Staff Regulations and Rules) that confers upon the Individual Contractor the status of a WHO staff member. The Individual Contractor understands that a false statement may result in the cancellation of any or all contracts, and/or the withdrawal of any offer of a contract, with WHO.

7 Research involving human participants. If and to the extent the work to be performed under this agreement includes surveys or interviews involving human participants (hereinafter referred to as "research"), the following shall apply:
7.1 Ethical Aspects
It is the responsibility of the contractor to safeguard the rights and welfare of human subjects involved in research performed under this agreement, 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. Prior to commencing any such research, the contractor shall ensure that (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained for all participants, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the contractor, and (d) any special national requirements have been met.
7.2 Regulatory Requirements
It is the responsibility of the contractor to comply with the relevant national regulations pertaining to research involving human subjects.
7.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the contractor shall make appropriate arrangements to eliminate or mitigate any negative consequences to subjects or their families resulting from the conduct of the research under this agreement. Such arrangements shall to the extent feasible include appropriate counseling, medical treatment and financial relief. The contractor furthermore undertakes to protect the confidentiality of the information relating to the possible identification of subjects involved in the research.

8 Compliance with WHO Policies. By entering into this agreement, the contractor acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing:
- Company Contractors shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by their employees and any other persons engaged by them to perform the work under the agreement; and
- Individual Contractors shall not engage in any conduct that would constitute a violation of the standards of conduct, as described in the WHO Policies.
Without limiting the foregoing, the contractor shall 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 contractor becomes aware. For purposes of this agreement, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Code of Conduct for responsible Research, (iv) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (v) 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:

5. Achèvement et livraison. Le contractant achève et livre les travaux à l'OMS (y compris tout rapport technique qui pourrait être requis) à la date prévue par l'accord ou à l'expiration de tout délai supplémentaire accordé par l'OMS en application de la condition générale 4 ci-dessus. Tout état financier requis est soumis au plus tard dans les trente (30) jours qui suivent. Si le calendrier de paiement prévu au recto de l'accord prévoit le paiement à la fin des travaux, celui-ci n'est effectué qu'après réception, sous une forme satisfaisante, de tous les livrables exigés aux termes de l'accord, y compris les rapports techniques et les états financiers.

6. Certification du statut des personnes physiques. Toute Personne Physique certifie qu'elle n'a pas actuellement et n'aura pas pour la durée du présent accord, de relation contractuelle avec l'OMS (y compris les bureaux régionaux de l'OMS, les bureaux de pays ou de projet, les programmes, centres ou entités où le personnel est soumis au Statut et au Règlement du Personnel de l'OMS) lui conférant le statut de membre du personnel de l'OMS. Toute Personne Physique comprend qu'une fausse déclaration de sa part peut entraîner l'annulation de tous les contrats, et/ou le retrait de toute offre de contrat avec l'OMS.

7. Recherches impliquant des êtres humains. Si et dans la mesure où les travaux à effectuer dans le cadre du présent accord incluent des études ou interviews impliquant des êtres humains (ci-après dénommés "recherches" ou "étude de sujets humains") les points suivants sont applicables:
7.1 Aspects éthiques
Il incombe au contractant de s'assurer qu'au cours des travaux effectués dans le cadre de cet accord et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code d'éthique ou a la législation du pays, ou, a défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Avant de commencer toute recherche, le contractant doit s'assurer que: a. les droits et le bien-être des sujets impliqués sont suffisamment protégés; b. le consentement libre et éclairé a été obtenu pour tous les participants, c. des experts indépendants désignés par le contractant ont évalué les risques et les avantages potentiels et ont jugé qu'ils s'équilibrent de manière acceptable et; d. toute exigence particulière de la réglementation nationale a été satisfaite.
7.2 Exigences réglementaires
Il incombe au contractant de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.
7.3 Protection des sujets humains
Sans préjudice des obligations lui incombant aux termes des lois en vigueur, le contractant prendra des mesures appropriées en vue d'éliminer ou d'atténuer toute conséquence négative pour les sujets ou leur famille résultant de la conduite des recherches dans le cadre de cet accord. Ces mesures comprendront, dans la mesure du possible, des conseils appropriés, un traitement médical et un dédommagement financier. Le contractant s'engage en outre à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études.

8 Respect des politiques de l'OMS. En concluant cet accord, le contractant reconnaît qu'il a lu les Politiques de l'OMS (telles que définies ci-dessous) et qu'il les accepte et convient de s'y conformer. En lien avec ce qui précède:
- les Personnes Morales doivent prendre des mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les Politiques de l'OMS, par leurs employés et par toute autre personne qu'elles ont engagées pour exécuter les travaux en vertu de cet accord; et
- les Personnes Physiques ne doivent pas adopter un comportement pouvant constituer une violation des normes de conduite, telles que décrites dans les Politiques de l'OMS.
Sans limiter la portée de ce qui précède, le contractant doit immédiatement signaler à l'OMS, conformément aux dispositions des Politiques de l'OMS applicables, toute violation réelle ou présumée dont il a connaissance concernant toute Politique de l'OMS. Aux fins du présent accord, l'expression « Politiques de l'OMS » signifie collectivement : (i) le Code d'éthique et de déontologie de l'OMS, (ii) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, (iii) le Code de conduite pour une recherche responsable, (iv) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles, et (v) 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

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AGREEMENT FOR PERFORMANCE OF WORK
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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.

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.

9. 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

- each Company Contractor warrants that it will: (i) 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 the work under the agreement, and (ii) 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 Company Contractor becomes aware; and
- each Individual Contractor warrants that he/she will: (i) 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 (ii) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Individual Contractor becomes aware.

9. Tolérance zéro pour l'exploitation et les abus sexuels. L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent accord :

- chaque Personne Morale garantit: i) 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 pour exécuter les travaux prévus au titre du présent accord, et (ii) 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
- chaque Personne Physique garantit: i) qu'elle 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 ii) qu'elle signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont elle a connaissance, conformément aux dispositions de la Politique

10. Tobacco/Arms Related Disclosure Statement. Company Contractors may be required to disclose relationships they may have with the tobacco and/or arms industry through completion of the WHO Tobacco/Arms Disclosure Statement. In the event WHO requires completion of this Statement, the Company Contractor undertakes not to permit work on the agreement to commence, until WHO has assessed the disclosed information and confirmed to the Company Contractor in writing that the work can commence

10. Déclaration relative à l'industrie du tabac/de l'armement. Il peut être demandé aux Personnes Morales de déclarer leurs 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. Dans les cas où l'OMS demande une telle déclaration, la Personne Morale s' engage à ne pas autoriser le commencement des travaux au titre de l'accord tant que l'OMS n' a pas évalué les informations communiquées et confirmé par écrit à la Personne Morale que ces travaux peuvent commencer

11 Anti-terrorism and UN sanctions; Fraud and Corruption. The contractor warrants for the entire duration of the agreement that,

(i) it is 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 it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity,

(ii) it 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 the agreement, and

(iii) the contractor 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 the agreement..

Any payments used by the contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent collusive or coercive practice shall be repaid to WHO without delay.

11 Anti-terrorisme et sanctions de l'ONU; fraude et corruption. Le contractant garantit, pour toute la durée de l'accord :

(i) qu'il n'est ni ne sera impliqué à l'égard de, ni associé à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité de l'ONU a désignée comme étant associée au terrorisme, qu'il ne fera aucun paiement à, ou ne soutiendra d'aucune autre manière, une telle personne ou entité, et qu'il ne conclura aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité ,

(ii) qu'il ne prendra 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 de l'accord , et

(iii) le contractant prendra 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 de l'accord.

Tout paiement utilisé par le contractant pour la promotion de toute activité terroriste ou de toute pratique illégale, de corruption, de fraude, de collusion ou de coercition doit être immédiatement remboursé à l'OMS.

12 Breach of essential terms. The contractor acknowledges and agrees that each of the provisions of general conditions 8, 9, 10 and 11 above 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:

(i) terminate this agreement, and/or any other contract concluded by WHO with the contractor, immediately upon written notice to the contractor, without any liability for termination charges or any other liability of any kind; and/or

(ii) exclude the contractor 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 violation of such provisions to WHO's governing bodies, other UN agencies, and/or donors

12. Violation de clauses essentielles. Le contractant reconnaît et accepte que chacune des dispositions des conditions générales 8, 9, 10 et 11 ci-dessus 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

(i) de résilier immédiatement cet accord, et/ou tout autre contrat conclu par l'OMS avec le contractant, moyennant une notification écrite adressée au contractant, 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

(ii) d'exclure le contractant 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 aux organes directeurs de l 'OMS, aux autres organismes des Nations Unies et/ou aux donateurs

13 Termination. WHO may terminate this agreement or any part thereof with immediate effect (in addition to any other rights or remedies to which WHO may be entitled, including the right to claim damages), on written notice to the contractor if the contractor is:

(i) in breach of any material obligation(s) under this agreement and, to the extent such breach is capable of being remedied, fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from WHO; or

(ii) adjudicated bankrupt or formally seeks relief of its financial obligations.

13. Résiliation. L'OMS peut résilier avec effet immédiat le présent accord ou toute partie de celui-ci (en plus de tous les autres droits ou recours dont l'OMS peut se prévaloir, y compris celui de réclamer des dommages-intérêts), moyennant une notification écrite adressée au contractant, si ce dernier :

(i) est en violation d'une (ou plusieurs) obligation(s) importante(s) du présent accord et, dans le cas d'une violation susceptible d'être réparée, manque de remédier à une telle violation dans les trente (30) jours suivant la réception d'une notification écrite de l'OMS envoyée à cet effet , ou

(ii) s'est déclaré en faillite ou a demandé officiellement à être exonéré de ses obligations financières,

14. Use of WHO name and emblem. Without WHO's prior written approval, the contractor shall not, in any statement or material of an advertising or promotional nature

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refer to this agreement or the contractor's relationship with WHO, or otherwise use the name (or any abbreviation thereof) and/or emblem of the World Health Organization.

15. **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 contractor's name and for Company Contractors, the country of incorporation, general information with respect to the work described herein and the 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

16. **Audit.** WHO may request a financial and operational review or audit of the work performed by Company Contractors under this agreement, to be conducted by WHO and/or parties authorized by WHO and the Company Contractor 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. In order to facilitate such financial and operational review or audit, the Company Contractor shall keep accurate and systematic accounts and records in respect of the work performed under this agreement.
The Company Contractor shall make available, without restriction, to WHO and/or parties authorized by WHO:

(i) the Company Contractor's books, records and systems (including all relevant financial and operational information) relating to this agreement; and

(ii)reasonable access to the Company Contractor's premises and personnel.

The Company Contractor shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Company Contractor to provide complementary information about the work performed under this agreement that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Company Contractor and related to the work performed under this agreement.

17 **Surviving provisions.** Those provisions of this agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply

18 **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.

19. **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 and/or as submitting WHO to any national court jurisdiction.

14. **Utilisation du nom et de l'emblème de l'OMS.** Le contractant n'a pas le droit, dans aucune déclaration ni aucun support à caractère publicitaire ou promotionnel, de faire référence au présent accord ou à sa relation avec l'OMS, ni d'utiliser d'une autre manière le nom (or toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

15. **Publication de l'accord.** Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence de cet accord et de publier, et/ou rendre public d'une autre manière, le nom du contractant ainsi que, le pays d'enregistrement si le contractant est une Personne Morale, des informations générales concernant les travaux décrits dans le présent accord et la valeur de l'accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent accord

16 **Vérification.** L'OMS peut demander qu'un examen ou une vérification de type financier et opérationnel des travaux effectués par les Personnes Morales en vertu du présent accord soit effectué(e) par l'OMS et/ou par des parties autorisées par l'OMS, et la Personne Morale s'engage à faciliter cet examen ou cette vérification. Cet examen ou cette vérification peut être effectué(e) à tout moment pendant l'exécution des travaux effectués au titre du présent accord, ou dans les cinq ans suivant l'achèvement des travaux. Afin de faciliter cet examen ou cette vérification de type financier et opérationnel, la Personne Morale doit tenir des comptes et des registres précis et systématiques sur les travaux effectués en vertu du present accord.
La Personne Morale doit mettre à la disposition de l'OMS et/ou des parties autorisées par l'OMS, sans restriction:

(i) les livres, les archives et les systèmes de la Personne Morale concernant le présent accord (y compris l'ensemble des informations financières et opérationnelles pertinentes); et

(ii) un accès raisonnable aux locaux et au personnel de la Personne Morale.

La Personne Morale doit fournir des explications satisfaisantes en réponse à toutes les questions découlant de la vérification et des droits d'accès susmentionnés

L'OMS peut demander à la Personne Morale de lui communiquer des informations complémentaires concernant les travaux exécutés au titre du présent accord qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'une vérification (interne ou externe) effectuée par la Personne Morale au sujet des travaux exécutés au titre du présent accord

17 **Dispositions restant en vigueur après la fin du contrat** Les dispositions du présent accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée dudit accord continueront de s'appliquer.

18 **Règlement des différends** Toute question concernant l'interprétation ou l'application du présent accord qui 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, déterminées selon le Règlement d'arbitrage de la Chambre de Commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale

19. **Privilèges et immunités.** Aucun des termes du présent accord 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

9/8/2019

ATTESTED

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

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UNIVERSITY OF ILLINOIS
URBANA-CHAMPAIGN • CHICAGO • SPRINGFIELD

CONTRACT BETWEEN
THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS
AND
KLE JAWAHARLAL NEHRU MEDICAL COLLEGE

ATTESTED

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

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UNIVERSITY OF ILLINOIS
URBANA-CHAMPAIGN • CHICAGO • SPRINGFIELD

Contract for Procurement of Services

ARTICLE 1. Identification of Parties

The parties to this contract are:

(a)The Board of Trustees of the University of Illinois, a body corporate and politic of the State of Illinois ("University"), on behalf of Pediatrics and (b) KLE Jawaharlal Nehru Medical College, a(n) Not-For-Profit Corporation with its principal office at Faculty of Medicine, KLE University, Kptcl Colony, Nehru Nagar, Belagavi Belagavi, Karnataka, India 590010 ("Vendor" or "Contractor").

ARTICLE 2. Scope of Services

2.1 **Services.** Vendor will perform the following "Services" and will obtain at Vendor's expense all necessary licenses and permissions necessary for Vendor's performance:

Support the participants and data-related activities for the project including, but not limited to: assisting with recruitment, administering the intervention, organizing supplies and intervention materials, daily management of study data, conducting in-clinic assessments, scoring data entry of assessments, and working with the University of Illinois at Chicago and Jawaharlal Nehru Medical College data managers to compile, clean, and recode data and other project-related activities as requested.

2.2. **Work Product.** As part of Vendor's performance of Services, Vendor will furnish to University the following work product ("Work Product"):

Data set

2.3. **Discrepancies/Questions.** If any discrepancies or questions arise during Vendor's performance of the contract, Vendor is responsible for obtaining written clarification from University's Technical Representative before providing the Services at issue. Vendor waives all claims for adjustment arising from Vendor's performance outside the scope of Services without a written contract amendment.

2.4. **Warranty.** Vendor warrants that the Services (i) will be performed in a timely, competent, workmanlike and professional manner and (ii) will conform to the contract specifications, documentation and requirements and to applicable industry standards for quality.

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ARTICLE 3. Term and Termination

3.1. **Term.** This contract shall not be binding until it is signed by both parties. The Effective Date of the contract shall be the last signature date appearing below. The term of this contract shall commence on the "Effective Date". Unless renewed by University in accordance with Section 3.2, this contract shall expire on 12/31/2020.

3.2. **Right to Renew.** This contract is not renewable.

3.3. **Termination for Cause.** A party that defaults in performance or commits a material breach of this contract ("defaulting party") shall have 10 days to cure the default or breach after receiving notice from the other party. The non-defaulting party may terminate this contract without further notice and pursue other available legal remedies if the defaulting party fails to cure the breach within the prescribed period, or within such other period of time that is agreed by the parties in writing.

3.4. **Termination for Convenience.** University may terminate this contract for convenience and without any cause by providing at least 30 calendar days' prior written notice to Vendor.

3.5. **Termination for Non-Appropriation.** This contract is subject to termination by University in any year for which the General Assembly fails to make an appropriation to make payments under the contract.

3.6. **Effect of Termination.** In the event of early termination for any cause, Vendor shall stop performance in accordance with the notice of termination and shall submit to University a final bill for Services performed to the date of termination. University is not obligated to pay Vendor for Services until Vendor provides all Work Product that is in progress or completed as of the date of termination. Vendor must comply with University's instructions to either destroy or return to University all information previously furnished to Vendor.

ARTICLE 4. Compensation

4.1. **Compensation.** University shall pay Vendor compensation at the rate of $7110 for Services performed to University's reasonable satisfaction in accordance with the Scope of Services set forth in Section 2.1 above and with the specifications and requirements set forth in Section 2.2 above, if any. University shall reimburse Vendor in accordance with University policy for expenses not included in the compensation rate only if preauthorized in writing by University's representative. Expenses shall be reimbursable only if submitted with all supporting documentation reasonably required by University. University's obligation for total

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compensation, including authorized expenses, shall not exceed $7,110.00 unless approved by written amendment to this contract in accordance with University policies and applicable law.

4.2. **Billing and Payment.** In order to be paid, Vendor must submit a proper invoice to University of Illinois, Invoice Processing Center, P.O. Box 820, Rantoul IL 61866 no more frequently than monthly. A proper bill must include: itemized detail, invoice number, invoice date, invoice amount, remittance address and the University purchase order number. University will either approve the bill for payment, or deny a bill with defects, in accordance with the State Prompt Payment Act (30 ILCS 540) (the "Act"). University will assign a new date of receipt to a bill resubmitted in proper form. University will pay interest on approved bills that are not paid within the time period prescribed by the Act. The rate of interest shall be the rate established in the Act on the date that payment becomes late within the meaning of the Act. University will not pay interest of $5 or less and may subtract any applicable discounts before payment.

4.3. **Withholdings.** University may withhold or may void any invoice to the extent University deems necessary to protect University from loss due to Vendor's: (a) unsatisfactory performance; (b) failure to pay subcontractors; (c) damage to University property; or (d) incomplete, inaccurate or unauthorized billing. University may withhold final payment until Vendor has performed all Services to University's reasonable satisfaction in accordance with the specification and requirements for the Work Product.

4.4. **Price Adjustments upon Renewal.** If renewals are permitted, Vendor must notify University at least 90 calendar days prior to the contract expiration date of any changes to rates and price schedules. Any rate changes shall be in accordance with Vendor's original quotation or response to solicitation. The parties will reflect any rate/price changes in a written contract amendment.

ARTICLE 5. Notices

5.1 **Delivery.** To be enforceable, all notices must be in writing and delivered to the party's representative(s) named below, appropriate to the nature of the notice, by either certified mail, return receipt requested, or commercial carrier with delivery receipt. Notices are effective upon receipt by the designated representative. A party may change its representative at any time by written notice to the other party.

5.2. **Directing Notices.** Vendor shall direct all general notices or matters of contract interpretation to University Contract Representative and notices involving technical or scheduling issues to University's Technical Representative. Vendor must include University's contract number or

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relevant purchase order number in any notice. Vendor shall direct all formal legal notices to the Board of Trustees.

University Contract Representative	Vendor Contract Representative
Nester Komolafe Purchasing Division 809 S. Marshfield, M/C 560 Chicago, IL 60612 Telephone: (312) 217-1682 Facsimile: (312) 996-3135 Email: nester@uic.edu	Shivaprasad Goudar KLE Jawaharlal Nehru Medical College Faculty of Medicine, KLE University Kptcl Colony, Nehru Nagar, Belagavi Belagavi, Karnataka, India 590010 Telephone: +91-831-2474200 Facsimile: +91-831-2472891 Email: sgoudar@jnmc.edu
University Technical Representative	**University Legal Notices**
Helene Gussin Pediatrics hgussin@uic.edu	The Board of Trustees of the University of Illinois Attn: Secretary of the Board 352 Henry Administration Building, MC-350 506 South Wright Street Urbana, Illinois 61801

ARTICLE 6. INSURANCE

Unless exempt by law, Vendor shall maintain the insurance coverages set forth below and shall provide evidence of such coverage to University's Contract Representative upon request. Vendor shall ensure that all subcontractors comply with the same insurance requirements. Subcontractors shall submit the required Certificate of Insurance through Vendor. Failure to comply with the insurance requirements constitutes a material breach of this contract.

With respect to the Commercial General Liability Insurance, Vendor shall name the Board of Trustees of the University of Illinois as an additional insured. In order to meet this requirement, wording substantially similar to the following must appear on the Certificate of Insurance: *The Board of Trustees of the University of Illinois is an additional insured for liability incurred by the University arising out of the activities of Vendor/Contractor and any of its subcontractors.* Vendor shall ensure that the relevant P.O. or Contract Number is indicated on the Certificate of Insurance.

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Worker's Compensation, including Occupational Diseases	
• Coverage A	minimum Illinois Statutory limits
◦ Coverage B	minimum $500,000 E.L. each disease minimum $500,000 E.L. each employee minimum $500,000 E.L. policy limit
☐ Check if "sole proprietor" and Workers' Compensation (Coverage A&B) are not applicable. NOTE: If company is in the construction business, trucking business operating at a construction site, or other hazardous occupation, 820 ILCS 185 of the Illinois Combined Statutes requires that even "sole proprietors" MUST obtain insurance.	
Commercial General Liability, including contractual liability	
◦ Each Occurrence	minimum $1,000,000
• General Aggregate	minimum $2,000,000 aggregate
◦ Products-Completed Operations Aggregate	minimum $2,000,000 aggregate
◦ Personal & Advertising Injury	minimum $1,000,000
◦ Fire Damage Legal Liability	minimum $100,000
Auto Liability (either personal or commercial as applicable)	
◦ Combined Single Limit OR	minimum $1,000,000 per occurrence
• Bodily Injury	minimum $1,000,000
• Property Damage	minimum $1,000,000

Umbrella liability insurance may be used to meet the minimum coverage requirements shown above.

Additional insurance requirements for this contract are checked below:

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☐ Professional Liability – Specialty Errors and Omissions	$1,000,000 per claim $3,000,000 annual aggregate
☐ Professional Liability – Medical Malpractice	$1,000,000 per claim $3,000,000 annual aggregate

When the services include any professional services, Vendor shall maintain professional liability insurance coverage for Vendor and its employees and agents to include coverage for errors, omissions, and negligent acts related to the rendering of such professional services with limits not less than $1,000,000 per claim and $3,000,000 annual aggregate. Coverage extensions shall include contractual liability. When policies are renewed or replaced, any retroactive date must coincide with, or precede commencement of services by Vendor or subcontractor under this contract. A claims-made policy that is replaced or not renewed must have an extended reporting period not less than two years.

☐ Employee Dishonesty	$150,000 each occurrence

Vendor shall furnish any original Certificate(s) of Insurance evidencing the required coverage to be in force on the date of this contract, and any renewal Certificate(s) of Insurance if coverage has an expiration or renewal date occurring during the term of this contract to the University of Illinois, Purchasing Division, 809 S. Marshfield, m/c 560, Chicago, IL 60612. University's receipt of a Certificate of Insurance does not constitute University's acknowledgment or agreement that insurance requirements have been met. Failure of University to obtain Certificate(s) or other insurance evidence from the Vendor shall not be deemed a waiver of these insurance requirements by University. Vendor's failure to comply with insurance requirements constitutes a material breach of contract terms.

ARTICLE 7. Indemnification

Vendor shall fully indemnify University, its officers, employees, trustees, students, and agents against all demands, claims, damages, liabilities, expenses and reasonable attorney fees and cost arising out of the performance of this Contract by Vendor, its employees, and agents. This indemnification obligation shall survive the termination or the cancellation of the Contract and any order made under it.

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ARTICLE 8. Subcontracts

Vendor shall provide an attachment listing all known or anticipated subcontracts with an annual value of $50,000 or more. The attachment shall include the proposed value of each subcontract and the name and address of the subcontractor. Vendor shall not subcontract any portion of the Services without University's prior written permission and shall promptly notify University of any proposed change in subcontractors, together with all relevant information requested by University.

ARTICLE 9. Confidentiality

9.1. **General.** Vendor must treat all information relating to this contract as confidential ("University Information"). Unless required by law, Vendor shall not disclose University Information to third parties or use University Information for any purpose other than in performing the Services except as authorized in advance in writing by University.

9.2. **Family Educational Rights and Privacy Act, 20 U.S.C. §1232g (FERPA).** Unless authorized by law or by written permission of the student, Vendor shall not disclose to any third party information concerning University students. Vendor shall protect all records containing student information in accordance with FERPA and University policy. In addition to other remedies, University may terminate this contract immediately upon information that Vendor may have violated this provision.

9.3. **Illinois Personal Information Protection Act, 815 Ill. Comp. Stat. 530 (PIPA).** If applicable, Vendor will cooperate in good faith with University to maintain security and integrity of *personal information* in compliance with PIPA.

9.4. **Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 C.F.R. parts 160 and 164.** If Vendor is University's *Business Associate*, as that term is defined by the HIPAA Privacy Rule at 45 C.F.R. §160.103, then Vendor agrees to the terms of the HIPAA Business Associate Agreement attached as Exhibit C.

ARTICLE 10. Rights in Work Product

10.1. **Title to Work Product.** Title to all Work Product made under this contract vests in University upon delivery by Vendor. University shall have the exclusive right to use Work Product for any purpose without further obligation to Vendor. Vendor represents that Work Product is original and does not infringe on third party rights. Vendor will not place any restrictive markings upon Work Product.

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10.2. **Pre-Existing Rights**. University shall not claim any interest in Vendor's materials, products, inventions or know-how existing prior to formation of this contract. Vendor grants to University a royalty-free, nonexclusive, irrevocable, worldwide license to make, use, sell, and to reproduce, distribute, prepare derivative works and perform, as the case may be, any pre-existing materials, products, inventions or know-how that are included by Vendor in the Work Product provided to University under this contract.

10.3. **Third Party Property**. Vendor shall not incorporate into the Work Product any third party property without University's prior written authorization. If University permits Vendor's use of third party property in the Work Product, Vendor must obtain for University a license at no cost to University that will enable University to use the Work Product without restriction. Vendor shall defend and indemnify University against all third party claims for infringements related to the Work Product unless otherwise expressly agreed by University in writing.

ARTICLE 11. Records Retention and Audits

11.1. **Maintenance of Books and Records.** Vendor shall maintain books and records that relate to performance of this contract and that support amounts charged for three years from the date of final payment or for such longer period of time as is necessary to complete ongoing or announced audits or to comply with any applicable federal requirements.

11.2. **Right of Inspection.** University may reasonably inspect Vendor's premises, facilities, equipment, and investigate the business reputation and other qualifications of Vendor and any of Vendor's subcontractors throughout the term of this contract.

11.3. **Litigation Hold Order Compliance.** Vendor shall, and shall cause Vendor's employees and subcontractors to, fully comply with any litigation hold order issued by University in anticipation of third party litigation relating to this contract. Vendor shall promptly retrieve, recover, preserve, and retain and, subject to legal privileges, deliver any information and documents, in any format, covered by a litigation hold order.

ARTICLE 12. General Terms

12.1. **Ambiguities.** Any rule of construction that would resolve ambiguities against the drafting party shall not apply in interpreting this contract

12.2. **Amendments.** No modification of this contract shall be effective unless made by a written amendment signed by each party's authorized signatory.

12.3. **Assignment.** Neither party may assign its obligations under this contract without the prior

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written consent of the other party.

12.4. **Authorized Signatories.** The individuals signing this contract on a party's behalf represent that they have the requisite authority and intent to bind that party to this contract.

12.5. **Choice of Law.** This contract shall be interpreted by application of Illinois law without regard to its conflicts provisions.

12.6. **Compliance with Laws.** Vendor shall perform all obligations under this contract in compliance with all applicable laws governing the performance. Breach of this provision constitutes a material breach of this contract.

12.7. **Counterparts/Facsimile Signatures.** This contract may be signed in counterparts. Facsimile signatures constitute original signatures for all purposes.

12.8. **Excluded Parties.** Vendor certifies that neither Vendor nor any of Vendor's directors, officers, employees, agents and subcontractors who may provide services pursuant to this contract (individually an "Agent") is presently debarred, suspended, proposed for debarment, declared ineligible or otherwise excluded from transactions with the U.S. Government or by any federal government agency. Vendor shall provide University immediate written notice if Vendor learns that this certification was erroneous when made or if Vendor or any of Agents hereafter becomes debarred, suspended, proposed for debarment, declared ineligible or otherwise excluded from transactions with the U.S. Government or by any Federal agency. Vendor further certifies that neither Vendor nor any Agents is presently subject to an investigation or proceeding to exclude either as a provider under Medicare or Medicaid or under any other federal or state health care program or under any third party insurance program, nor is currently excluded or debarred from submitting claims to Medicare or Medicaid or to any other federal or state health care program or to any third party insurer. University may terminate this contract immediately without any penalty to University if either of these certifications was erroneous when made or becomes no longer valid during the term of this contract.

12.9. **Force Majeure.** A party is excused from performing its obligations under this contract when conditions beyond its control and unforeseen by the parties make its performance commercially impractical, illegal, or impossible. Conditions of excuse include, but are not limited to: natural disasters, strikes, fires, war, terrorism and threats of terrorism, government actions, and acts or omissions of third parties. So long as the conditions continue, the party whose performance is affected shall keep the other party fully informed about the conditions and the prospects of their ending.

12.10. **Headings.** Headings in this contract are intended only to assist with readability and are not

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substantive.

12.11. **Independent Contractor.** The parties are independent contractors with respect to each other. Nothing in this contract is intended to create any association, partnership, joint venture, or agency relationship between them.

12.12. **Integration.** This contract with its attachments, amendments and incorporated references constitutes the parties' entire agreement regarding the subject matter.

Attachments include:

Exhibit A - State Clauses and Certifications (Included below)

Optional Attachments:

☐ Exhibit B - Financial Disclosures & Conflicts of Interest

☐ Exhibit C - Business Associate Agreement

☐ Exhibit D - (federal clauses)

☐ Exhibit E - Joint Commission CMS Clauses

☐ Other:

12.13. **Jurisdiction.** Any claims against University must be filed in accordance with the Illinois Court of Claims Act.

12.14. **Severability.** If any provision of this contract is held by a court of competent jurisdiction to be unenforceable, the provision shall be severed from this contract so long as severance does not affect the enforceability or essential purpose of the remainder of the contract.

12.15. **Sovereign Immunity.** By entering into this contract, University does not waive the sovereign immunity or any other defenses and immunities afforded to it by Illinois and federal law.

12.16. **Use of Name.** Vendor shall not use University's name or protected marks for any commercial purpose without University's advance written consent.

12.17. **Waiver.** The failure of either party to enforce any provision of this contract shall not waive the party's right to later enforce the provision or the contract.

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS

By: _____

Kevin Fair, Associate Director of Purchasing
2019.12.17 13:21:21 -06'00'

KLE JAWAHARLAL NEHRU MEDICAL COLLEGE

By: _____
for

Printed: Dr. N S. Mahantashetti

Title: Principal, J.N. Medical College, Belagavi

Date: 26/12/2019

Approved as to legal form by Office of University Counsel on 1/16/15

Text

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NON FEDERAL Foreign Research Subaward Agreement

Prime Recipient	Subrecipient
Institution/Organization ("Prime Recipient")	Institution/Organization ("Subrecipient")
Name: The University of North Carolina at Chapel Hill	Name: K L E Society's Jawaharlal Nehru Medical College
Prime Award No. OPP1192462	Subaward No. 5116269
Awarding Agency Bill & Melinda Gates Foundation	Amount Funded This Action $165,205US
Prime Recipient PI Jeff Stringer	Subrecipient PI Shivaprasad Goudar
Subaward Period of Performance: Budget Period From: January 1, 2020 To: August 31, 2020	Estimated Project Period (if incrementally funded): From: January 1, 2020 To: September 30, 2021

Project Title

Limiting Adverse Birth Outcomes in Resource-Limited Settings (LABOR) Trial

Reporting Requirements ☑ See Attachment 4

Terms & Conditions

1) Prime Recipient hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are (check one): ☐ As specified in Subrecipient's proposal dated [ ]; or ☑ as shown in Attachment 5. In its performance of the subaward work, Subrecipient shall be an independent entity and not an employee or agent of Prime Recipient.
2) Prime Recipient shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost-sharing), subaward number, and certification as to truth and accuracy of invoice. *Invoices that do not reference Prime Recipient's Subaward Number shall be returned to Subrecipient.* Invoices and questions concerning invoice receipt or payment should be directed to appropriate party's Financial Contact as shown in Attachments 3A & 3B.
3) A final statement of cumulative costs incurred, including cost-sharing, marked "FINAL" must be submitted to the Prime Recipient's Financial Contact, as shown in Attachments 3A & 3B, NO LATER THAN 30 days after the subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.
4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against Subrecipient.
5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator, as shown in Attachments 3A & 3B. Technical reports are required as shown below, "Reporting Requirements."
6) Matters concerning the request or negotiation of any changes in the terms conditions or amounts cited in this subaward agreement, and any changes required prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachments 3A & 3B.
7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directs, to the extent allowed by law.
8) Either party may terminate this subaward with thirtv days written notice to the appropriate party's Administrative Contact as shown in Attachments 3A & 3B. Prime Recipient shall pay Subrecipient for termination costs as allowable under Prime Award.
9) No Cost Extensions require the approval of the Prime Recipient. Any request for a no cost extension should be addressed to and received by the Administrative Contact, as shown in Attachments 3A & 3B, not less than thirty (30) days prior to the desired effective date of the requested change.
10) The Subaward is subject to the terms and conditions of the Prime Award (Attachment 6) and other special terms and conditions, as identified in Attachment 2.
11) By Signing below Subrecipient makes the certifications and assurances shown in Attachment 1. Subrecipient also assures that it will comply with applicable regulatory requirements specified in the Prime Award and Attachment 2.

By and Authorized Official of Prime Recipient:	By an Authorized Official of Subrecipient:
Name Terry Magnuson Date March 3, 2020	Name Date 27/2/2020
Title Vice Chancellor for Research	Title Dr. N.S. Mahantashetti

UNC date last updated: July 18, 2016

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Attachment 3B
Research Subaward Agreement

Subaward Number: 5116269

Subrecipient Contacts

Institutional/Organization ("Subrecipient")

Name: KLE Society's Jawaharlal Nehru Medical College
Address: JNMC Campus
Nehru Nagar
City: Belgaum State: Karnataka ZipCode: 590010
EIN No.: Institution Type: Non-Profit Organization SAM.gov Reg (•) Yes ( ) No
Performance Site Same Address as Above? ( ) Yes ( ) No DUNS No.:
If no, is the performance site the same as PI address below? ( ) Yes ( ) No 650251213

Administrative Contact

Name: Dr Shivaprasad S Goudar
Address: Professor of Physiology and Research Coordinator
Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research (Deemed-to-be-University) Jawaha
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-94481 26371; +91-831-24 Fax: +91-831-2472891
Email: sgoudar@jnmc.edu

Principal Investigator

Name: Dr Mrutyunjaya B Bellad
Address: Professor of OBGYN
KLE Academy of Higher Education and Research
Jawaharlal Nehru Medical College, Nehru Nagar
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-9481 24893 Fax: +91-831-2472891
Email: mbbellad@hotmail.com

Financial Contact

Name: Mr Amit P Revankar
Address: Network Manager and Data Coordinator
Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research (Deemed-to-be-University) Jawaha
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-98441 74337 Fax: +91-831-2472891
Email: amit@jnmc.edu

Authorized Official

Name: Dr Niranjana S Mahantashetti
Address: Principal
KLE Academy of Higher Education and Research (Deemed-to-be-University)
Jawaharlal Nehru Medical College, Nehru Nagar
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-94481 57237 Fax: +91-831-2472891
Email: niranjanasn@yahoo.com; principal@jnmc.edu

ATTESTED

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

UNC date last updated: July 18, 2016

BILL & MELINDA GATES *foundation*

GRANT AGREEMENT
Investment ID OPP1192462

AGREEMENT SUMMARY & SIGNATURE PAGE

GRANTEE INFORMATION	
Name:	University of North Carolina at Chapel Hill
Tax Status:	Public Charity pursuant to U.S. IRC § 509(a)(1) You confirm that Your receipt of the Grant Funds will not affect Your classification as a public charity under Section 501(c)(3) of the United States Internal Revenue Code of 1986, as amended and agree to notify the Foundation immediately of any change to this classification.
Mailing Address:	104 Airport Drive, Suite 2200 Campus Box 1350 Chapel Hill, NC, 27517
Primary Contact:	Jeffrey Stringer, Ph.D, Dept of OB/GYN, jeffrey_stringer@med.unc.edu

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, WA 98102
Primary Contact:	Megan Carey, Program Officer, Enteric Diarrheal Diseases, Megan.Carey@gatesfoundation.org

AGREEMENT INFORMATION	
Title:	Limiting Adverse Birth Outcomes in Resource-Limited Settings (LABOR) Trial
"Charitable Purpose":	to produce a low-cost device that can be deployed in developing world labor wards to substantially improve outcomes through better risk assessment and early diagnosis.
"Start Date":	Date of last signature.
"End Date":	October 31, 2021
This Agreement includes and incorporates by this reference:	This Agreement Summary & Signature Page and: • Grant Amount and Reporting & Payment Schedule (Attachment A) • Terms and Conditions (Attachment B) • Proposal Narrative (date submitted October 2, 2018) • Results Framework and Tracker (date submitted September 20, 2018) • Budget (date submitted September 24, 2018)

THIS AGREEMENT is between University of North Carolina at Chapel Hill ("*UNC*" "*You*" or "*Grantee*") and the Bill & Melinda Gates Foundation ("*Foundation*"), and is effective as of the date of last signature. Each party to this Agreement may be referred to individually as a "*Party*" and together as the "*Parties.*" As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

DocuSigned by:
Trevor Mundel
DD5444F322CE4A9...

By: Trevor Mundel
Title: President of Global Health
October 25, 2018
Date

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

DocuSigned by:
Terry Magnuson
01549B4CZZC1480...

By: Terry Magnuson
Title: Vice Chancellor for Research
November 1, 2018
Date

ATTESTED

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

GRANT AGREEMENT
Investment ID OPP1192462

ATTACHMENT A
GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT
The Foundation will pay You up to the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE
Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING
You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

REPORTING & PAYMENT SCHEDULE				
Investment Period	*Target, Milestone, or Reporting Deliverable*	*Due By*	*Payment Date*	*Payment Amount (U.S.$)*
	Countersigned Agreement	November 15, 2018	Within 15 days after receipt of countersigned Agreement	$2,500,000.00
	Milestone: Submission of Sub-Award Budgets	March 31, 2019	April 2019	$3,000,000.00
Start Date - 10/31/19	Progress report	December 31, 2019	January 2020	$6,000,000.00
11/1/19 - 10/31/20	Progress report	December 31, 2020	January 2021	$1,064,320.00
Start Date - End Date	Final report	November 30, 2021		
			Total Grant Amount	**$12,564,320.00**

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

Research Subaward Agreement Amendment

Prime Recipient	Subrecipient
Institution/Organization ("Prime Recipient") Name: The University of North Carolina at Chapel Hill Address: Office of Sponsored Research 104 Airport Drive, Suite 2200, CB# 1350 Chapel Hill, NC 27599-1350 Email: ResAdminOSR@unc.edu	Institution/Organization ("Subrecipient") Name: K L E Society's Jawaharlal Nehru Medical College Address: Nehru Nagar Belagavi-590010, Karnataka INDIA
Prime Award No.: OPP1192462 Prime Recipient Principal Investigator: Jeff Stringer	Subaward No.: 5116269 Subrecipient Principal Investigator: Shivaprasad Goudar
Effective Date of Amendment: January 1, 2020	Amendment No.: 1

Amendment(s) to Original Terms and Conditions

Action:

1) Period of Performance: To extend the period of performance to October 31, 2020.

2) Compensation: To authorize incremental funding in the amount of US $724,613. The total amount of the Agreement per Amendment 1 is not to exceed US $889,818.

The following documents are incorporated into this Subaward Agreement Amendment as noted:

Attachments:

Attachment A: Notice of Award
Attachment B: Budget

Administrative Contact Information:
Contact Name: Chester Williams
The University of North Carolina at Chapel Hill
Office of Sponsored Research
104 Airport Drive, Suite 2200, CB#1350
Chapel Hill NC 27599-1350
Email: resadminosr@unc.edu
Fax: (919) 962-5011/3352
Phone: (919) 966-3411

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of Prime Recipient:	By an Authorized Official of Subrecipient:
Earleen F. Sharrock Digitally signed by Earleen F. Sharrock Date: 2020.06.17 12:17:13 -04'00'	
Name: on behalf of Terry Magnuson Date Title: Vice Chancellor for Research	Name: Dr. N.S. Mahantashetti Date: 8/6/2020 Title: Principal, J.N. Medical College, Belagavi

UNC date last updated: July 18, 2016

ATTESTED

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

BILL & MELINDA GATES *foundation*

GRANT AGREEMENT
Investment ID OPP1192462

AGREEMENT SUMMARY & SIGNATURE PAGE

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Mailing Address:	104 Airport Drive, Suite 2200 Campus Box 1350 Chapel Hill, NC, 27517
Primary Contact:	Jeffrey Stringer, Ph.D, Dept of OB/GYN, jeffrey_stringer@med.unc.edu

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, WA 98102
Primary Contact:	Megan Carey, Program Officer, Enteric Diarrheal Diseases, Megan.Carey@gatesfoundation.org

AGREEMENT INFORMATION	
Title:	Limiting Adverse Birth Outcomes in Resource-Limited Settings (LABOR) Trial
"Charitable Purpose":	to produce a low-cost device that can be deployed in developing world labor wards to substantially improve outcomes through better risk assessment and early diagnosis.
"Start Date": "End Date":	Date of last signature. October 31, 2021
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THIS AGREEMENT is between University of North Carolina at Chapel Hill ("*UNC*" "*You*" or "*Grantee*") and the Bill & Melinda Gates Foundation ("*Foundation*"), and is effective as of the date of last signature. Each party to this Agreement may be referred to individually as a "*Party*" and together as the "*Parties.*" As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

DocuSigned by:
Trevor Mundel
DD5444F322CE4A9...

By: Trevor Mundel
Title: President of Global Health
October 25, 2018
Date

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

DocuSigned by:
Terry Magnuson
81549B4C22C1460...

By: Terry Magnuson
Title: Vice Chancellor for Research
November 1, 2018
Date

ATTESTED

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

KLE Academy of Higher Education and Research
Jawaharlal Nehru Medical College, Belagavi
Women's and Children's Health Research Unit

Ref No. MDC/JNMC/2020-21/ **Date:28.01.2021**

TO WHOMSOEVER IT MAY CONCERN

Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi has conducted a research project titled – **"Evaluating the WHO Labour Care Guide in clinical settings"** sponsored by World Health Organization, Geneva, Switzerland.

Project Period: September 2019 to December 2019

National Collaborators: Fakir Mohan Medical College and Hospital, Balasore, Odisha.

Dr Shivaprasad S Goudar
Professor of Physiology, J N Medical College &
Director-Research, KLE Academy of Higher Education and Research
(Deemed-to-be-University)
Nehru Nagar, Belagavi-590010
Mobile: +91-94481 26371
Email: sgoudar@jnmc.edu

Address for Correspondence:
KLE Academy of Higher Education and Research, J.N. Medical College,
Nehru Nagar, Belagavi-590 010, Karnataka
Phone: +91-831-2474200 / +91 831 244 4190 Fax: +91-831-2472891

ATTESTED

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

KLE Academy of Higher Education and Research
Jawaharlal Nehru Medical College, Belagavi
Women's and Children's Health Research Unit

Ref No. MDC/JNMC/2020-21/ **Date:28.01.2021**

TO WHOMSOEVER IT MAY CONCERN

Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi is conducting a research project titled – **"Reducing Anemia in Pregnancy in India: The RAPIDIRON Trial" in collaboration with Thomas Jefferson University, Philadelphia, PA, USA and funding by Children's Investment Fund Foundation (CIFF), UK.**

Project Period: September 2020 to August 2023

National Collaborators: Sawai Man Singh Medical College, Jaipur, Rajasthan

Dr Shivaprasad S Goudar
Professor of Physiology, J N Medical College &
Director-Research, KLE Academy of Higher Education and Research
(Deemed-to-be-University)
Nehru Nagar, Belagavi-590010
Mobile: +91-94481 26371
Email: sgoudar@jnmc.edu

WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT • JNMC
J.N Medical College, BELAGAVI.

Address for Correspondence:
KLE Academy of Higher Education and Research, J.N. Medical College,
Nehru Nagar, Belagavi-590 010, Karnataka
Phone: +91-831-2474200 / +91 831 244 4190 Fax: +91-831-2472891

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, BELAGAVI

AND

KARNATAKA INSTITUTE FOR DNA RESEARCH DHARWAD

FOR COLLABORATIVE RESEARCH ON

HUMAN GENETICS AND MOLECULAR MEDICINE

Academy of Higher Education and Research Deemed-to-be University

ATTESTED

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

Karnataka Institute for DNA Research Government of Karnataka

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA42738093916101S
Certificate Issued Date	:	12-Oct-2020 12:50 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM3/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL08809288480645085
Purchased by	:	KAHER REGISTRAR
Description of Document	:	Article 12 Bond
Description	:	M O U
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KAHER REGISTRAR
Second Party	:	KARNATAKA INSTITUTE OF DNA RESEARCH
Stamp Duty Paid By	:	KAHER REGISTRAR
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Shri Siddhivinayak Banjara Must.
C/o. K. T Patil Building Chavat Galli, BGM

Authorised Signature

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding is entered into and executed on this the 07rd day of October 2020 by and between

...2

KLE Academy of Higher Education and Research, Deemed-to-be University, BELAGAVI

ATTESTED

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

Karnataka Institute for DNA Research, Government of Karnataka

PBLG

financial implications will be negotiated in good faith by both the parties on a project to project basis.

3. KAHER will recognize eligible faculty members at KIDNAR as PhD guide for its students who wish to enroll for PhD Course. Joint Research shall be conducted by the faculty and the students in the field of Human Genetics.

4. Both the parties shall form a Joint Committee comprising of designated members equal in number from either party to explore new opportunities for research in the field of molecular genetics and associated medical subjects.

5. The Joint Committee shall decide the operation of research projects, streaming of the funds, outcome of the research and other incidental terms.

6. The Parties may invite each other to participate in activities, working groups, conferences and seminars that are not directly part of this MoU but that may be relevant to it, in conformity with respective applicable rules.

7. The information or data submitted or acquired during the research OR the information or data which is the outcome of the research activity, is the common property of both the parties and neither party is permitted to transfer such information or data to any third party without the prior written consent of the other party.

8. All credentials arising of the joint research work undertaken under this MoU will be shared appropriately by both the parties as decided by the Joint Committee.

ATTESTED

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

Karnataka Institute for DNA Research
Government of Karnataka

PBG

IN WITNESS WHEREOF the parties herein above have signed and executed the above MOU on the day and date herein above mentioned in the presence of following witnesses.

Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

FIRST PARTY

Director
Karnataka Institute for DNA Research
Pavate Nagar, Dharwad-580 003

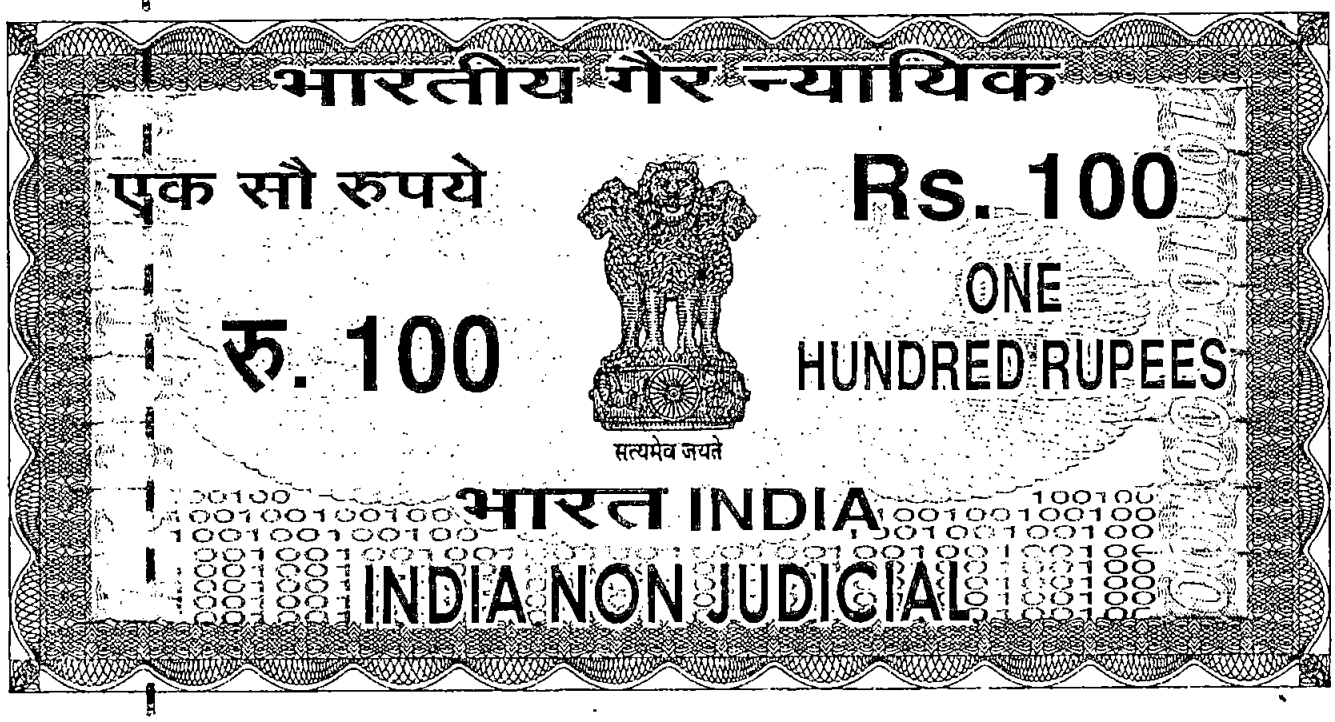
SECOND PARTY

WITNESSES

1. DR. GANGA S. PILLI

2. Dr. Suyamindra S. Kulkarni

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



ગુજરાત ગુજરાત GUJARAT

BU 943836

નંબર : 14539 રૂ.૧૦૦

તારીખ : ૧૫ માર્ચ ૨૦૧૯

નામ : LAMBDA THERAPEUTIC RESEARCH LTD.
Plot No. 38, Near Silver Oak Club,

ઠેકાણું : S.G. Highway, Gota,
Ahmedabad-380061

કે. જી. ફોતરીયા

લા. નં. એસ.બી. ૪૨૮, ૪૨૯/૧૯૯૯

બી-૪, સ્નેહા ફ્લેટ, મેમનગર, અમદાવાદ ના સ્ટેમ્પવેન્ડર

સહીનો સહી.....

Clinical Trial Agreement

BETWEEN

Lambda Therapeutic Research Ltd.
Lambda House, Plot No. 38,
Survey No. 388, Near Silver Oak Club,
S.G. Highway, Gota,
Ahmedabad-382481,
Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad -380054
Gujarat, India.

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

139

AND

Dr. Santosh Dhananjay Hajare
KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Institute")

AND

Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
(Hereinafter referred to as the "SMO")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN

Lambda Therapeutic Research Ltd.
Lambda House, Plot No. 38,
Survey No. 388, Near Silver Oak Club,
S.G. Highway, Gota,
Ahmedabad-382481,
Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad -380054
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND

Dr. Santosh Dhananjay Hajare
KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Institute")

AND

Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
(Hereinafter referred to as the "SMO")

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of **Intas Pharmaceuticals Ltd.;**

Intas Pharmaceuticals Ltd. has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled **"A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment."** and, The Principal Investigator, having reviewed the Protocol for the Clinical Trial, the Investigator brochure and sufficient information regarding the Investigational Product in order to evaluate and determine its interest in participating in the Clinical Trial, wishes to participate in the Clinical Trial and the Principal Investigator assures that he/she has sufficient authority, Competence and experience in conducting clinical trials.

The Institution has facilities and personnel with the requisite skills, experience, and knowledge required to support the performance of the Clinical Trial by the Principal Investigator; and the Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1. Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	Tacrolimus Lipid Suspension for enema 4 mg/vial **(Test Product)**
"CRF"	means the case report form in a format prepared by Sponsor and documenting the administration of the Investigational Product to Clinical Trial Subjects as well as all tests and observations related to the Clinical Trial;
"CRO"	Contract/Clinical Research Organization

"Declaration of Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.
"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
"ICH GCP"	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"SAE"	Serious Adverse Event as defined by ICH GCP.
"Site"	The site at which the Clinical Trial is conducted.
"Study"	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.
Agent	shall include, but shall not be limited to, any person providing services to a Party under a contract for services or otherwise, to include without limitation any pharmacist, clinical chemist, nurse or other health professional.
Agreement	means this agreement comprising its clauses, schedules and any appendices attached to it, including the Protocol and including any amendments to the Agreement agreed between the Parties;
Auditor	means a person who is authorized to carry out a systematic review and independent examination of clinical trial related activities and documents to determine whether the evaluated clinical trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the Protocol, the Standard Operating Procedures of Sponsor and/or CRO, ICH GCP and the applicable regulatory requirements.
Clinical Trial	means the investigation to be conducted at the Trial Site in accordance with the Protocol
Clinical Trial Subject	means a person enrolled to participate in the Clinical Trial

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

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Confidential Information	means information provided by a Party (the Disclosing Party) to the other Party (the Receiving Party) or to any other of such Receiving Party's employees or agents, and means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of the Disclosing Party or the Disclosing Party's Affiliates that are provided in connection with this Agreement or the Clinical Trial. Sponsor's Confidential Information shall include Clinical Trial data, results, or reports created by Institution, Principal Investigator, or Research Staff in connection with the Clinical Trial (except for a Clinical Trial Subject's medical records); and cumulative Clinical Trial data, results, and reports from all sites conducting the Clinical Trial.
Intellectual Property Rights	means patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;
Investigational Product	Means the Study Drug identified above and the control material, as further detailed in the Protocol.

2. Investigator/Institution responsibilities

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, current Schedule Y of DCGI, and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members 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 Investigator is responsible for notifying LAMBDA of such change in a timely manner.

2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.7 During the performance of the Clinical Trial and for a period of 10 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not 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 LAMBDA on a regular basis;

c) ensuring direct access by monitors, auditors and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) to allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda'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.

i) In case if any of the delegated research staff at site gets relieved from his/ her services the Investigator/ Institution shall appoint the relevant function or make the alternate arrangement in shortest possible time so as the trial related activity does not get affected.

j) The Investigator / institution shall make and retain records (study documents including source data/patient medical documents) of the Clinical Trial as required by the Protocol, applicable Law, and in accordance with the Institution's standard archiving procedures (SOP). Institution will retain such records for a minimum of fifteen (15) years from the date of database closure or as per the local regulatory requirements. Such archival shall be done either at the institution or at the third party agency. At least Sixty (60) days prior to the expiry of such retention period, Sponsor/ CRO will contact Institution. If requested by

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Sponsor/CRO, Institution shall retain the records for a longer period of time at Sponsor's expense.

k) Place of archival of retention records and the amount incurred should be discussed during the CTA execution as per Institution's standard archiving procedures (SOP). Cost of Archival fees, if applicable will be paid at the time of close out before close out visit.

l) If any services or activities including the diagnostic test or clinical procedure required by the protocol are being outsourced by Investigator /Institution to the other facilities/ institutions then this should clearly be documented via an agreement / MOU. The Investigator /Institution shall provide LAMBDA with a copy of the said agreement / MOU.

2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor and to the Ethics Committee. The 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 i.e. within 24 hours (of occurrence or knowledge or becoming aware) to LAMBDA, IEC and Institution by Investigator; and further follow up reporting will be done as per the regulatory guidelines prescribed in Schedule-Y(of occurrence or knowledge or becoming aware) to ethics committee and Regulatory Authority (DCGI) via first draft report. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the 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 deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambda undertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3. CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI, and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage

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and disposal of the Compound. Sponsor/Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the 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.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4. Performance standards of the work to be conducted by the Investigator

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **2-3** Eligible Patients within **1** month; minimum expected recruitment rate from the site is **2-3 patients per month** on average. 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 depending on the complexity of the project and date of initiation; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within **3** working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, current Schedule Y and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5. Payment terms

5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B.

5.2 3 Original wet ink copies of the CTA would be in place.

6. Period of validity of the Agreement

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

6.2 However following matters shall survive even after expiry/termination of the agreement:

a) Archival of study documents including source data as referred to in para 2.7 and 14
b) Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
c) Confidentiality as per para 11

6.3 In case of early termination of trial at site, due to any clause, data and documents are to be archived at Site (PI's /Institution /third party). This shall be discussed during the execution of CTA and should be clearly documented in the CTA. . The said data must be archived for at least fifteen (**15**) years or for the period required by applicable regulatory authority following termination of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements. In case of early close out/termination the validity of the agreement would remain for 5 years.

7. Data ownership / Intellectual property rights

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

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7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and this agreement, irrespective of the PI presence in the institution. Institution will allow regulatory authorities, sponsor and CRO to perform inspections of study data. In case the PI has to leave the institution, the PI should handover charge of the study to any other designee in form of document and forward all future communications received to institute pertaining to trial. PI is responsible to update CRO and / or sponsor for this change and all applicable communications, henceforth. Designee will execute all PI responsibilities, henceforth. In case of change in institution management, the institute will inform CRO and / or sponsor

8. Publication

8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9. Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

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9.3 Sponsor (on behalf of LAMBDA) will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor (on behalf of LAMBDA) will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor (on behalf of LAMBDA) will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

10. Compensation / Insurance

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.

11. Confidentiality

11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any

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purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) is already in the public domain at the time of disclosure

b) becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) was previously known to the Institution or the Investigator as evidenced by written documents

d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12. Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13. Independent Contractor

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14. Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

a) Investigator or Institution fails to recruit patients within **60 days** of site initiation visit.
b) The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.
c) Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.
d) LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.
e) The total number of patients required to be randomised is reached before the end of the recruitment period.
f) The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.
g) The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA. On termination / completion of trial or expiration of this Agreement all unused Investigational Product shall, either be returned to the Lambda Pharmacy /
Sponsor or disposed of in accordance with the Protocol or the Sponsor's written Instructions.

14.1 On Completion, Early Termination of the Trial:

a) Upon completion of the Clinical Trial (whether prematurely or otherwise) the Principal Investigator and Sponsor shall co-operate in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis and drawing appropriate conclusions.

b) The Investigator/ Institute shall permit authorized representatives of the Ethics Committee and Competent Authorities to have access to, copy and verify information relating to the Clinical Trial, as required by and in accordance with applicable Law. Furthermore Sponsor and/or CRO acknowledges and agrees that the Institution executive management (or a local review board appointed by such management) will have the right to audit the performance of the Clinical Trial at the Trial Site. Institution acknowledges that the Clinical Trial is subject to inspection by regulatory authorities worldwide and that such inspections may occur after the completion of the Clinical Trial.

c) On completion, termination of the Trial, following termination or expiration of this Agreement Investigator/ Institution shall upon request immediately deliver to the LAMBDA/Sponsor all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes. Furthermore the Site Parties shall immediately deliver to the Sponsor any equipment provided to them for the conduct of the trial at the site.

d) Upon notice of termination of trial or this Agreement, Investigator/Institution will not recruit and/or enroll additional Clinical Trial subjects, and will cooperate with the Sponsor in the orderly discontinuation of the Clinical Trial, including, without limitation, discontinuing Investigational Product as soon as medically appropriate, allowing Sponsor and/or CRO access to records and facilities as required for Clinical Trial close-out procedures at mutually agreed times, and requiring Principal Investigator to complete any actions required in compliance to ICH GCP and Local regulations by the role Principal Investigator.

e) In all circumstances causing the early termination of trail and, LAMBDA shall confer with the Principal Investigator/ Institution and use their best endeavours to minimize any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial. Parties (LAMBDA, Investigator and Institution) agree that in case of early termination of this Agreement, they will in good faith make arrangements concerning the continuation of the treatment of the enrolled patients if such is in their medical best interest. Furthermore the Investigator and Institution shall ensure that the rights, safety and well-being of the trial subjects are protected in all circumstances.

14.2 Termination of Trial/ Trial Agreement by Investigator or Institution:

a) The Institution and/or the Principal Investigator shall notify the Sponsor and/or CRO if the Principal Investigator ceases to be associated with the Institution where the Clinical Trial will be conducted or if he/she is otherwise unavailable to continue as Principal Investigator, and Institution and/or Principal Investigator shall use all reasonable endeavours to find a qualified successor acceptable to the LAMBDA, subject to the Principal Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care. In the event Principal Investigator is for whatever reason unable or unwilling to appoint a successor personally, the Institution will have the right to recommend a suitable successor and the Institution will make all possible efforts to appoint the successor/ PI to conduct the study.

b) In case if the Institution is unable to carry out the ongoing trial for any reasons the Institution will make all the necessary arrangement to ensure that the enrolled trail patient

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can receive the best medical care, In case if the patients still want to continue in the study, they can be referred to the other Institution/ Investigator. In all such cases Institute/investigator will be responsible for the safety follow and further medical care of the patients for the period as appropriate as per the study drug and the nature of the study. In case if the trail subject do not wish to continue with the trial at referred site and the site has to be closed data retention, patient safety and maintenance of study data for the required period as required by the applicable regulatory authority would be the responsibility of the Institution.

15. Record retention

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, Schedule Y and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO 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. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.

15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least fifteen (**15**) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than **30** days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16. Representation and Warranty

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17. Laws and Jurisdiction

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17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18. Notice

18.1 All notices shall be delivered to the following addresses:

CRO

Address:	Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388 Near Silver Oak Club, S.G. Highway, Gota Ahmedabad-382481, Gujarat, India
Telephone:	+91 79 4020 2020
Fax:	+91 79 4020 2021/22
Contact person:	**Dr. Kiran Marthak**

Investigator	:	Dr. Santosh Dhananjay Hajare
Address	:	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka, India.
Telephone	:	0831-2470400
Fax	:	0831-2493099

Institution Contact Person:	:	Dr. M.V.Jali
Address	:	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka, India.
Telephone	:	
Fax	:	NA
SMO Name	:	Doclin Clinical Research Services
Address	:	445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
Telephone	:	+91-9164256468
Contact Person	:	Mr. Maruti Patil

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

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18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19. Miscellaneous

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

19.6 If SMO is involved in any study related activities, PI / Institution needs to provide the copy of MOU/Agreement to CRO during / before the time of execution of CTA. The MOU provided should have the clarity on the responsibilities of Investigator /Institute and SMO.

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: _____ **Date:** 8 Jul. 2019

Mr. Rajiv Bhattacharya/ Mr. Gautam Vaghela
Clinical Trial Management
Lambda Therapeutic Research Ltd.

Witness:

Sign: _____ **Date:** 03/Jul/19

Witness Name : Mr. Naresh Khemani, AGM, Finance
Witness Address : Lambda Therapeutic Research Ltd.,
Lambda House, Plot No. 38,
Survey No. 388, Near Silver Oak Club,
S.G. Highway, Gota,
Ahmedabad-382481, Gujarat, India.

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Institute: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India

Sign: _____ **Date:** 19.07.2019

Dr. M.V.Jali – MD & CEO

Witness:

Sign: _____ Date: 19-07-2019

Witness Name: Ravanna Sperandi

Designation: Assistant coordinator

Department/Work Unit:

Institute Name: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India.

SMO: Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008

Sign: _____ Date: 12 Jul 2019

Mr. Maruti Patil – Managing Director

Witness:

Sign: _____ Date: 12 Jul 2019

Witness Name: Akshay Thombare

Witness Address:

Investigator: Dr. Santosh Dhananjay Hajare

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Principal Investigator: Dr. Santosh Dhananjay Hajare

Sign: _____ **Date:** 15-Jul-2019

Witness:

Sign: _____ **Date:** 15-Jul-2019

Witness Name : Dr. Arvind Jadhav
Witness Address : KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India.

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Schedule A

Study Protocol

Protocol No: 0979-17

A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment."

Schedule B

Budget and Payment Agreement

(I) Budget

S.No	Visit Number	Screening/ washout	Treatment Period					Follow up period		Total
		1	2	3	4	5	6	7	8	
	Week Number	W-1	W-0 Baseline	W-1	W-2	W-3	W-4/EOT	W-6(2 Week post treatment follow up	W-8(EOS 4 week post treatment follow up	
	Days	D-7 TILL D-1	D-0	D-7(+_2)	D-14(+_2)	D-21(+_2)	D-28(+_2)	D-42(+_2)	D-56(+_2)	
	Activity									
1	PI Grant	7000	4000	4000	4000	4000	5000	5000	5000	38000
2	CRC Grant	5000	3500	3500	3000	3000	3000	3000	3500	27500
3	ECG-12 lead	600					600			1200
4	Serum pregnancy test	650					650		650	1950
5	Urine pregnancy test	250								250
6	Drug urine scan	200								200
7	Urine analysis	500					500		500	1500
8	Stool test for CD toxins	600								600
9	Hematology	800					800		800	2400
10	Blood/serum Biochemistry(Including S.electrolytes)	1800					1800		1800	5400
11	X-ray (Chest PA view)	500								500
12	Immunology (S.anti HIV antibodies, Hbsag, and antibodies against HCV)	2000								2000
13	UCDAI Score(including colonoscopy)		10000				10000			20000
14	PK assessment		800	800	800	800	800		800	4800
15	Histopathology (Biopsy) [Optional]		1000							1000
16	Institutional OverHeads (25%)	3000	1875	1875	1750	1750	2000	2000	2125	16375
17	Patient Conveyance	1000	1000	1000	1000	1000	1000	1000	1000	8000
	Total	23650	22425	11175	10550	10550	26150	11000	16175	131675

Note:

Archival Fees: LAMBDA will pay the Institute / Investigator/Payee towards archival fees INR 1,50,000/- for 15 yrs. on behalf of sponsor.

Screen Failures: LAMBDA will pay the Institute/Investigator towards screen failure payment of INR 10,000/- for each screen failure up to the maximum of 20% of total patients screened at the site. All screen failure patients payments will be made post LPLV.

PK Sample will be collected only from the patients randomized in test arm.

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(II) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) LAMBDA will pay a sum Rs. **One Lakh Thirty One thousand Six hundred and Seventy Five** (in words) for every complete and evaluable patient as defined in the payment schedule.

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 completely and accurately
- baseline evaluations done as per protocol

c) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc), the budget will be evaluated according to the number of visits completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

d) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

e) Any other parties designated by you (including Radiology, Local Laboratory & Cardiology, etc) will be managed and paid by you.

f) The **Ethics Committee fee** will be paid by the Sponsor, and it is separate from per patient grant as mentioned in budget.

g) Central Laboratory costs will be paid by Sponsor.

h) For Screen failure patients, the payment will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before dosing on Day 1 will be paid for screening visit. Reimbursement for screen failures will be at the amount indicated on the screening visit of the schedule-B budget, not to exceed One (1) screen failure(s) paid to four (4) subject(s) randomized. Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

i) 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.

j) **Patient conveyance/compensation** will be paid by Sponsor, and is included in budget as mentioned. TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." **GST applicable as per union budget rules.**

k) All Services provided by the site under this Agreement are taxable under the laws related to Goods & Service tax in India (GST) and it is required to be charged at the rate of 18%, as may be amended from time to time. The Sponsor / CRO (applicable word as per agreement should be used) undertake to provide Patient Visit Tracker on monthly basis (on last day of the month) to CRCs for the trial and on the basis of the tracker site shall raise invoice for the month. The invoice shall be in accordance with the terms of Rule 5 of the Tax Invoice, Debit and Credit Notes Rules of Goods & Service Rules 2017.

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l) Payment for the final invoice raised by the site will be released at the time of site close out. LAMBDA will release payment within 30 days from the receipt of invoice.

m) LAMBDA will pay the Institute / Investigator/Payee towards archival fees **INR 1, 50,000/-** for 15 yrs. on behalf of sponsor.

n) LAMBDA will pay the Institute/Investigator towards screen failure payment of **INR 10,000/-** for each screen failure up to the maximum of **20%** of total patients screened at the site.

o) All medical and hospital bills related to SAE management for the SAEs related to IMP to be paid by the Sponsor/Lambda.

p) The last amount payable will be considered as Final Payment. Final Payment will be paid during / after site close out visit. Sponsor will release payment within 40 days from the receipt of invoice.

q) Payment reconciliation will be made before the final payment to sites.

r) Adhoc payments will be made as per actuals (subjected to the approval from management and sponsor).

Should the trial terminate prematurely, any payments made by Sponsor exceeding the amount actually earned will be promptly refunded to Sponsor (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

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 Institution & PI. Details of Payee are:

Payment through Cheque:	
Name of Payee:	**Doclin Clinical Research Services**
Address of Payee:	445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
PAN / TAN Number:	**AZXPP8818R**
GST Number:	**29AZXPP8818R1ZP**

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. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) Per Patient Fee, Payment Schedule and Terms

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

   The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

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- all study related activities such as conduct of visits and CRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like ECG, X-ray, Slit lamp examination etc)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses
- usage of internet while filling of eCRF
- miscellaneous (telephone, fax, courier, etc)
- all overhead or any incidental costs.

Not included are (which are separate and in addition to per patient payment):
- EC submission fee

2. In the event that the LAMBDA/Sponsor requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the Sponsor under this Agreement will be done within 30 days following receipt of the corresponding invoice (complete in all respects) from the Investigator to Sponsor through LAMBDA. All such payments will be made by A/C Payee Cheques to the Institution/Investigator. (Can also be paid through wire transfer under case to case basis)

4. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA/Sponsor. These additional tasks will be submitted to LAMBDA/Sponsor in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA/Sponsor and are subject to prior written approval by LAMBDA/Sponsor, which, in its turn, must obtain prior written approval from Sponsor.

5. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA/Sponsor will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, Sponsor has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to Sponsor any amount by which amounts advanced by the Sponsor exceed the adjusted Trial Cost.

6. The CRO/Sponsor may withhold all or part of any amounts in the event of:

(1) failure of the Investigator/Institute to complete the services according to the Protocol;
(2) failure to provide LAMBDA with requested documentation:
(3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

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Authorised Signatory

INDIA STAMP DUTY MAHARASHTRA

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of 19th July 2019 ("Effective Date") between Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400018 ("Novartis") which expression shall mean and include its successors and assigns of the ONE PART;

AND

KLES Dr. Prabhakar kore hospital and MRC, , located at *Nehru Nagar Belagavi* ("Institution") registered under the provisions of Bombay Public Trust Act, 1950 and having its address at *Nehru Nagar, Belagavi, Karnataka, 590010* which expression shall mean and include its successors and assigns of the SECOND PART;

AND *Dr. Shivakumar Patil* as clinical practitioner in the field of *Dermatology*, acting in the role of principal investigator ("Principal Investigator") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "Party" and jointly as the "Parties".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the following drug: QGE031 (hereafter the "Study Drug") in accordance with a protocol entitled A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines, CQGE031C2302 and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study,

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

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1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

(d) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

(e) any "Applicable Law(s)" being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.

(f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Code of Conduct, Novartis global Antibribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

PROTOCOL

2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

APPROVALS

The Study shall not commence until:

(a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis and the competent Ethics Committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

DURATION OF THE STUDY

The Study shall commence on *1 Dec 2018*, subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *27 July 2021* or as may be extended by a formal writing between the parties in that behalf

TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon 9 May 2019 ('Effective Date') and shall expire upon 8 May 2022 (both days inclusive) unless extended or terminated in terms of this Agreement.

4.2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

4.3 In the event that the Principal Investigator decides to no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis as soon as possible, and [illegible] within 30 days prior to such termination. It is clarified that Principal Investigator shall

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6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "**Sub-Investigators**") to assist in the conduct of the Study. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("**Study Subjects**") and undertake in particular to have it executed by competent resources.

6.2 Study Site

The Study shall be conducted at the premises of Institution at the *KLES Dr. Prabhakar kore hospital and MRC,* located at *Nehru Nagar, Belagavi* : (hereinafter the "**Study Site**").

6.3 Use of Study Drug:

Novartis shall provide QGE031 (hereinafter called "**Study Drug**") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;

(b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;

(c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(d) shall fully comply with all the responsibilities set out under the law;

(e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and

(f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 **Study Subject consent and entry into Study:** Before entering a Study Subject into the Study, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;

(c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;

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[illegible] before any [illegible] of the Study, [illegible] may be his/her legal representative] has given his or her Informed Consent to the [illegible] the information described in Clause 9.4, (to be signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the study, and in accordance with Applicable Laws. An example ICF is attached hereto as Annex 3;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;

(g) comply with the procedures described in the Protocol in relation to that Study Subject; and,

(h) provide details of the proposed Study Subject to Novartis.

9.5 Study Subject Recruitment

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

9.6 Recordkeeping, Reporting, Access and Inspections

(a) Recordkeeping, Reporting

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Study Drug and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").

(ii) Maintain a copy of all documents related to this Study for the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) as required by applicable laws and regulations.

(iii) Meet with a representative of Novartis to discuss the progress of the Study; and Notify Novartis immediately upon discovering any significant violations of the Protocol.

(iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,

(v) Cooperate with Novartis in all their efforts to monitor the Study and to support Novartis in all matters of data collection, verification and discrepancy resolution

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[illegible] Ensure [illegible] records of Study Subjects are [illegible] in a known and accessible location during the period set out here-above.

(iii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;

(iv) be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

6.6 Access and Inspection

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

(i) Examine and inspect the Institution's facilities required for performance of the Study; and

(ii) inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Sponsor will maintain the confidentiality of any subject-identifiable medical records.

(iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any designated person within 24 hours, allow Novartis to be present at the inspection/action or participate in any response to the inspection/action; and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.

(iv) Grant access to Novartis or its representative to visit periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site in order to proceed with any and all monitoring activities required for the Study.

(v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.

(vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.

(vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.7 Reporting: The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Study; and

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(b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.

(c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 Reporting of Safety Information:

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.6 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

(a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Study Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.9 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) he Study Drug

(e) the study related equipments on returnable basis listed in Annexure 1

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6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

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In the case of [illegible] in a clinical trial subject or in the event of [illegible] trial related death of the subject, Novartis will provide [illegible] to the extent and in the manner under the applicable laws.

The Institution and Principal Investigator ("Indemnifying Party") will indemnify and hold harmless Novartis from and against any and all suits, claims, damages, losses, settlements, penalties, fines, costs and expenses, (including attorneys' fees, collectively, "Damages") of whatever kind or nature (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place a Study start.

COMPENSATION

In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1

Novartis reserves the right to terminate the Agreement immediately if no subjects have been recruited at the Study Site by *16 Feb 2020.*

Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator control. Reimbursement for expenses related to screening failures, patient travel, and local lab test will be made according to the Payment Schedule in Annex 1.

The Principal Investigator shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Each invoice shall specify the Study Code. Novartis shall make payments into the account indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of invoice from the Institution.

EQUIPMENT

If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator strictly on a returnable basis as detailed in Annex 1 The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution and/or the Investigator: The Equipment shall only be used for the conduct of the Study in accordance with the Protocol [illegible] and until Study is completed or discontinued.

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

purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

10.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

10.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

11.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the *KLES Dr. Prabhakar kore hospital and MRC/Dr. Shivkumar Patel* shall notify the relevant Ethics Committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines

11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.

11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement except to reimburse the Institution for such reasonable costs and non-cancellable obligations which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.

11.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

12. INTELLECTUAL PROPERTY

12.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

12.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.

12.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.

12.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

13. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility 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 which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

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PUBLICATION

Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

a to ensure the accuracy of the presentation or publication;

b to ensure that proprietary information is not inadvertently divulged;

c to enable intellectual property rights to be secured;

d to enable relevant supplementary information to be provided.

Authorship of any publications relating to the Study shall be determined by mutual agreement.

Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.

If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.

Except as otherwise required by law or regulation, neither Party shall release or distribute any materials or information containing the name of the other Party or any of its officers, agents or employees without the prior written consent by an authorised representative of the non-releasing Party.

CONFIDENTIALITY

All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "**Information**") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.

The confidentiality obligations set out above shall not apply to:

a Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

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b Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information, its collection or creation did not occur during or in connection with the Study;

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

NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the ad given in this Agreement

Mr. K. Muruganantham

GDO Trial Monitoring,

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road, Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Email: murugananthan.k@novartis.com

or to such other address as may have notified to the other party in writing.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Pa prior written consent, except that Novartis may (a) assign its rights and obligations under Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement i entirety to a successor to all or substantially all of its business or assets to which this Agree relates. Any permitted assignee will assume all obligations of its assignor under this Agree (or related to the assigned portion in case of a partial assignment). Any attempted assignme contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agree will be binding upon and inure to the benefit of the Parties and their respective successors permitted assigns.

18. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform an its obligations under this Agreement without the prior written consent of Novartis. Any consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunc

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherv in any one or more instances shall be deemed to be or construed as a further or continuing wa of any such term, provision or condition, or of any other term, provision or condition of Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the par with respect to the subject matter hereof. No amendment to this Agreement will be effective binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor collaborator who is involved in the performance of the Study has been debarred under the including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, D and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by Institution in connection with any work to be performed for or on behalf of Novartis. If at time after the execution

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KLE Academy of Higher Education and Research, BELAGAVI

CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

TRANSPARENCY/DISCLOSURE

For all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and

(b) other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding clinical or marketed products of Novartis, regardless of whether such are subject to the disclosure.

The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India without restricting any right of appeal.

DATA PROTECTION

A form regarding the disclosure of the Principal Investigator's personal data together with the general provisions regarding any personal information processed by the Institution under this Agreement is attached as Annex 2.

COUNTERPARTS

This Agreement may be executed in two or more counterparts each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY in relation with trial procedures while in all other instances the agreement shall prevail.

ATTESTED

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

Dr. Prabhakar kore hospital and MRC

By: _____

Name: Dr. M V Jali

Title: MD & CE KLES Dr. Prabhakar Kor Hospital and MRC

Date: 26/07/2019

_____

_____

_____

2nd July 2019

_____

umar Patil

_____

akumar Patil

Professor/Consultant

25/07/2019

ATTESTED

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

[redacted]

[redacted] and MRC

[redacted] Kangeyda Patil

[redacted]

[redacted] Number of Study Subjects: 5 randomized patients

[redacted] provided to Institution / Principal Investigator:

- [redacted] grometer
- [redacted] Pads - It would be retrieved from site post database lock is achieved.
- [redacted] Machine - It would be retrieved from site post database lock is achieved

[redacted] Schedule:

	Screening		Double blind treatment												
[redacted]	1	20	110	120	130	140	150	160	170	180	190	200	210	220	
[redacted]	-4	-1	R	4	8	12	16	20	24	28	32	36	40	44	
[redacted]	16800	2800	6000	5000	5000	5000	3500	3500	5000	3500	3500	3500	3500	3500	3
[redacted]	4000	3000	5000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3
[redacted]	2000	2000	3000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2
[redacted]	[redacted]	[redacted]	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	15
[redacted]	[redacted]	[redacted]	3750	2750	2750	2750	2375	2375	2750	2375	2375	2375	2375	2375	23
[redacted]	[redacted]	[redacted]	19250	14250	14250	14250	12375	12375	14250	12375	12375	12375	12375	12375	123

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	post treatment follow up			
Visit	240/EoT/TD	310	320	1999/EOS? PSD
Week	52	56	60	64
Protocol Procedures	6200	5000	5000	5700
Investigator Fees	4000	3000	3000	4000
Coordinator Fees	2000	2000	2000	2000
Unblinded Pharmacist fee	1500	1500	1500	1500
Institutional Overhead @ 25%	3300	2750	2750	3175
TOTAL (INR)	17000	14250	14250	16375
TOTAL COST 1 PT	275375			

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory.
- Sponsor shall reimburse patient's travel cost per protocol visit will be upto 1000 INR for which institution/PI shall provide original invoice along with the supporting bills.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.

ATTESTED

- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India Tax regulations) and GST will be paid on providing valid tax invoice

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

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date: Belagavi/25/07/2019

Name: Dr. Shivakumar Patil

Principal Investigator

ATTESTED

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

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

"Personal Information or Data" means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

"Sensitive Personal Information or Data" – constitutes a subset of Personal Information and relates to of an individual's (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual's name in combination with the individual's (a) Social Security number, (b) alien registration number, (c) driver's license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother's maiden name; and as applicable under local laws.

"Data Subject" – and identified or identifiable person who's Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable perosn is one sho can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological ,mental, economic, cultural or social identity.

"Processing" means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

"Institution Third Parties" – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject's legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution's Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:
Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

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Prof. Dr. V.A.KOTHIWALE

c. Obligations with Respect to Institution Third Parties.

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are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Part that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreem to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

(a) Without limitation of any provision of this Agreement, the parties agree to comply wit applicable Laws governing the privacy and security of Personal Information that Institu shall create, acquire, access or receive as a result of this Agreement, to the extent that Laws apply to either party.

(b) Institution agrees to implement administrative, technical and physical security measure protect Personal Information, from (i) unauthorised or accidental destruction, (ii) t forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthor alteration, copying access; or (vi) any other unauthorised processing.

(c) Security measures implemented by Institution must take into account (i) the purpose of data processing, (ii) nature and extent of the processing, (iii) assessment of possible risk the data subject; and (iv)current industry best practices and state of the art technolog including but not limited to encryption of information at rest and in transit. Secu measures shall be reviewed on a periodic basis and updated as required.

(d) All email communication with Novartis, especially those involving trial related informati should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutio email Ids), if any must be discussed with Novartis and a secure communication solution, mutually agreed and in line with Novartis' security standards, is implemented.

(e) Institution shall not sub-contract any of its rights or obligations without the prior writt notification to Novartis. In the event that any Institution Subcontractor shall have acce to Personal Information, such access shall be permitted under a need-to-know basis an only to the extent required for the due performance of Institution's obligations. Institutio shall enter into Agreements with its' subcontractors that contain privacy and securit provisions that are equivalent to the provisions under this Agreement.

(f) Institution shall ensure that personnel who will be undertaking the Processing of Novarti Personal Information, including that by Institution's Third Party (if any) have appropriat skills and privacy and security training to handle Sensitive Personal Information.

(g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, un-reconstructable and indecipherable.

(h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

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

I / We, the undersigned Institution and Principal Investigator for study number CQGE031C2302 decl that I have received a copy of;

(a) Novartis global Antibribery Policy

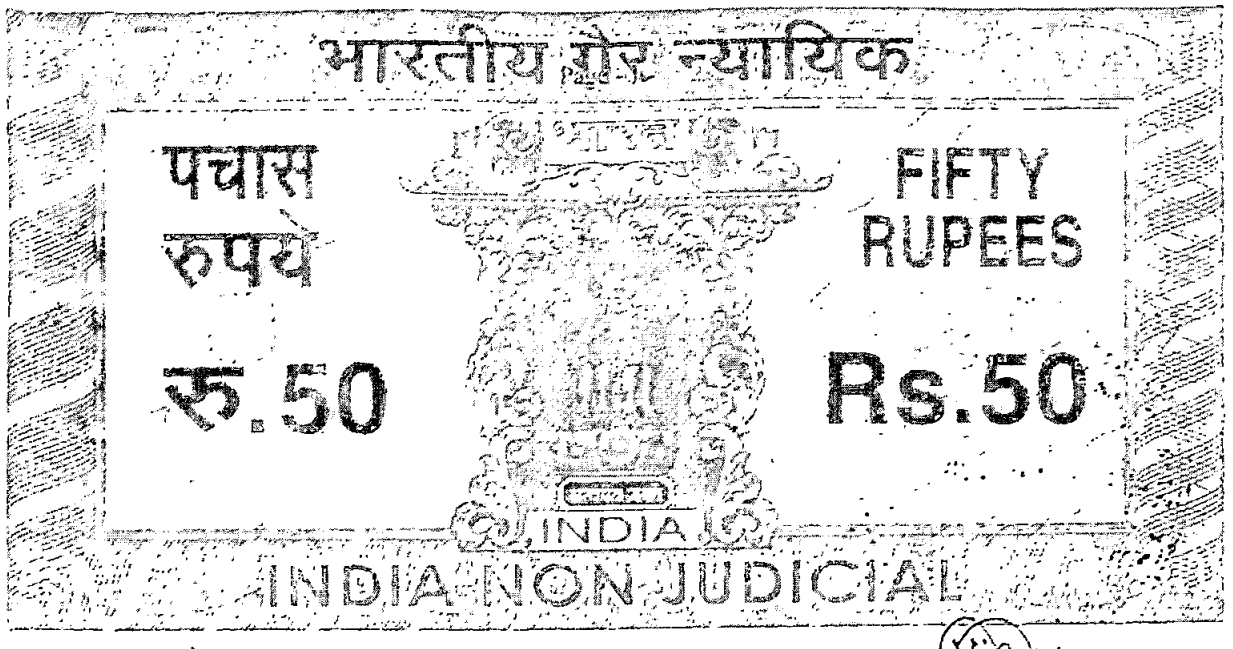
(b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

KLES Dr. Prabhakar kore hospital and MRC	Dr. Shivakumar Patil
By:	By:
Name: Dr. M-V Jali	Name: Dr. Shivkumar Patil
Title: MD & CEO	Title: Consultant Dermatologist / PI
Date: 26/07/2019	Date: 25/07/2019

ATTESTED

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



తెలంగాణ तेलंगाना TELANGANA
S.No:434 Date:08/07/2019 Rs.50/-
To : MADHAVA RAO MOLABANTI
S/o : LATE M VENKATESWARLU
FOR WHOM:-M/S.BIOLOGICAL E.LIMITED.
P/o:-HYDERABAD.

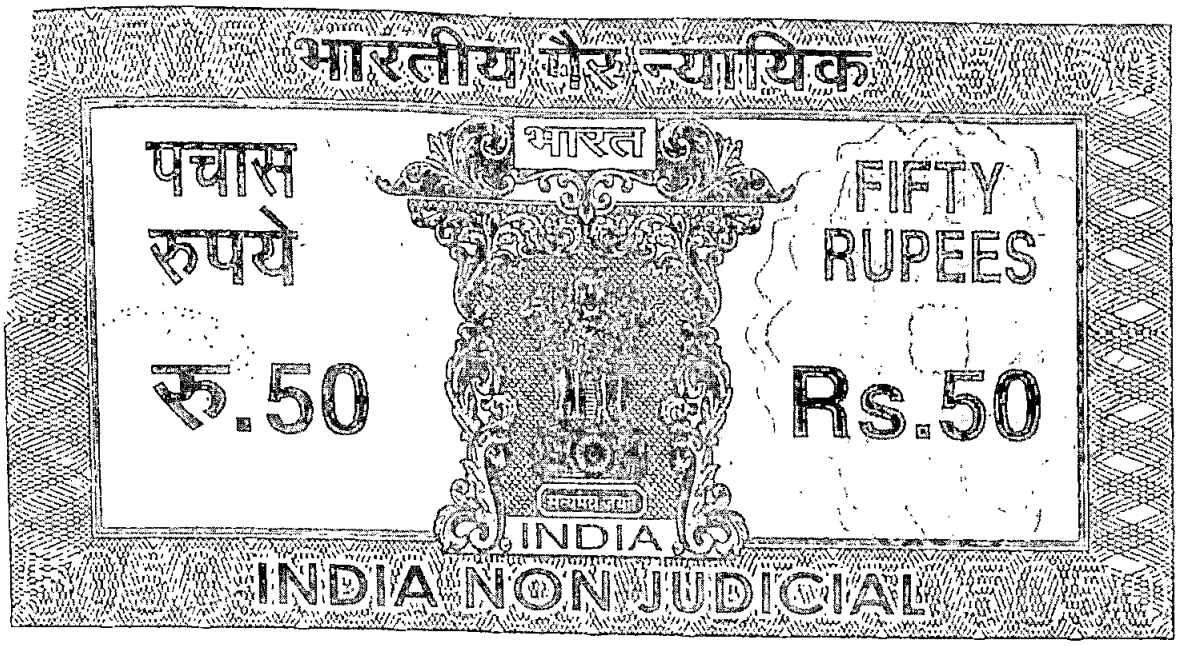
G 668219
The Advocates' Co-op Society
[illegible]

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement(the "**Agreement**")is made on 19th July, 2019 ("**Effective Date**") by and between **Biological E. Limited**, a company incorporated under the Companies Act, 1956 and having its registered office situated at 18/183, Azamabad, Hyderabad - 500020, Telangana, India ("**Sponsor**"), of the First Part; and **Dr. N.S. Mahantshetti**, a registered medical practitioner holding MCI registration number **22164**, currently working as Professor in Department of Pediatrics, KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum, Karnataka, India ("**Principal Investigator**") of the Second Part; and **KLEs JNMC Dr Prabhakar Kore Hospital,** Belgaum, Karnataka, India a hospital established registered under the laws of India, having its place of business at Nehru Nagar, Belgaum - 590010, Karnataka, India represented by its Medical Director ("**Institution**") Third Part

ATTESTED

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



తెలంగాణ तेलंगाना TELANGANA

B 900218

S.No: 7697 DATE:08/07/2019 RS: 50/-
SOLD TO : MADHAVA RAO MOLABANTI
S/O LATE M.VENKATESWARLU
FOR WHOM :- M/S BIOLOGICAL E. LIMITED R/O HYD

The Advocates' Co-op Society
Rep.By N Madhusudhan ,Licenced stamp Vendor,
Lic.No.16-10-10/2015, Ren No.16-10-17/2018.
Metropolitan criminal courts. Nampally,
Telangana State Phone No-040-23313246

WHEREAS,

A. The Sponsor is a biopharmaceutical company, which develops, manufactures and markets innovative vaccines and biologics. Biological E. Limited has developed the live attenuated Measles and Rubella vaccine developed by Biological E. and received marketing authorization by DCG(I), the present study is a phase IV Clinical Trial for obtaining additional safety data and to be conducted in twelve study centres;

B. The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;

C. The Sponsor has already identified the Principal Investigator based on his experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

D. The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed his willingness to the Sponsor to conduct the proposed Study;

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E. The Sponsor shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the Sponsor; and

F. The Principal Investigator has obtained and shall maintain in full force and effect all permissions, sanctions and approvals from the Institution and relevant governmental and regulatory authorities to undertake and conduct the Clinical Trial;

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

1. Definitions

1.1 "**Study**" or "**Clinical Trial**" shall mean study entitled:

"A multicenter single arm non-comparative Phase-IV post marketing study to Evaluate the safety and tolerability of Biological E's Live, Attenuated Measles-Rubella Vaccine (MR) in 9-12 month old Healthy Infants" and all the title amendments thereto as the Parties may from time to time agree in writing.

1.2 "**Protocol**" shall mean:

The description of the Study mentioned in the Study protocol number **BECT048/MRV-PIV/CTP-02** and all amendments thereto as the Parties may from time to time agree in writing.

1.3 "**Study Drug**" or "**Investigational Drug**" shall mean:

Biological E's Live, Attenuated Measles-Rubella Vaccine (MR) (Manufactured by Biological E. Ltd.).

1.4 "**Ethics Committee**" shall mean:

An independent body or an Institutional Ethics Committee, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

2. Responsibility of the Principal Investigator and the Institution

2.1 The Institution agrees to provide full support to the Principal Investigator who is working in Department of Pediatrics in the Institution, to conduct the Clinical Trial in its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, Co-ordinators and other persons with prior consent of the Sponsor, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.2 The Principal Investigator and Institution shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the Sponsor strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Institutional Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services,

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Govt. of India; Drugs and Cosmetics Act 1940 and Rules, gazette notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**"); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide Sponsor a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.3 The Principal Investigator along with any co-investigator employed/assigned in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:

(i) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

(ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Sponsor; and

(iii) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to the Sponsor.

2.4 Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the Sponsor, Chairman of Ethics Committee and licensing authority within twenty four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.

2.5 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of the Ethics Committee, Head of the Institution and to the licensing authority of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events, as the case may be.

2.6 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of Ethics Committee, licensing authority and to the Head of the Institution within fourteen (14) calendar days of occurrence of such serious adverse events.

2.7 In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any latter stage, the Principal Investigator/Institution shall provide notice to the Study subjects, Ethics Committee and Sponsor at least thirty (30) days before Principal Investigator intends to stop/withdraw from the Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator, from among the consultants of the Institution. The Sponsor shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Sponsor shall be required to agree to the terms and conditions of this Agreement. In the event Sponsor does not approve such new principal investigator, the Study will be terminated immediately and no further payment shall be

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made to Principal Investigator and the Institution. Upon such termination, Institution shall (i) ensure appropriate therapy and follow-up for enrolled Study subjects; (ii) maintain all Study related documents for such time as may be required by Sponsor and shall take measures to prevent accidental or premature destruction of these documents and (iii) undertake to complete the Study on all the enrolled subjects as per approved Protocol.

3. **Conduct of Clinical Trial**

3.1 The Sponsor shall appoint it's employee to monitor the Clinical Trial and also reserves it's right to nominate any other person as monitor.

3.2 Principal Investigator shall enroll the allotted number of subjects in a period of 60 calendar days from the date of study site initiation. It is hereby clarified that no payment shall be made to the Principal Investigator, if the Study subject is not participating in that particular visit.

3.3 Principal Investigator and the Institution agrees that if Principal Investigator cannot conduct and complete the Study to the satisfaction of the Sponsor within the time prescribed by the Sponsor on the agreed number of subjects as per clause 3.2 above, the Sponsor may at its sole discretion and without prejudice to its rights under this Agreement, send a notice to the Principal Investigator and the Institution to discontinue the Study. The Principal Investigator and Institution agrees to cease recruiting subjects for the Study immediately upon receiving such notice from the Sponsor to stop recruiting the subjects for the Clinical Trial.

3.4 Principal Investigator shall ensure that the Audio Visual recording of the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Sponsor by the Principal Investigator, who shall further obtain audio visual informed consent form duly signed by each of the subjects/Legally acceptable representatives on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio-visual recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, at the request of the Sponsor, Principal Investigator shall handover a copy of such recording for regulatory compliance or any order.

3.5 The Study of the Sponsor is being entrusted to the Principal Investigator and Institution directly by the Sponsor as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and Institution's experience as a qualified testing facility in the Clinical Trial. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Sponsor herein. All items received from the Sponsor, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator throughout the period of the Clinical Trial and thereafter for a period of fifteen (15) years after the Sponsor has discontinued its Study or such longer period as required by Applicable Laws &

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Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from Sponsor before destruction of such data.

3.6 Principal Investigator agrees to assume all the legal obligations of the Sponsor for the Study related duties and functions under this Agreement and the Protocol.

3.7 Principal Investigator/Institution shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. Institution and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

3.8 Principal Investigator represents and warrants that he has obtained and shall maintain in full force and effect all the necessary approvals, permissions and sanctions from the Institution, Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial.

4. Study Drug

4.1 The Sponsor will provide the Study Drug to the Principal Investigator/ Institution free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Sponsor only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Sponsor and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Sponsor in writing to the Principal Investigator. Principal Investigator and Institution jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Sponsor in compliance with Sponsor's instructions and all Applicable Laws & Guidelines.

4.2 The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the safety and tolerability of the Study Drug and that the Clinical Trial shall not constitute complete treatment to cure any disease.

5. Visit and Inspection

5.1 The Sponsor or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

i. examine and inspect the Institution's facilities whenever Principal Investigator is conducting Study;
ii. inspect and copy all data and work products relating to the Study, and
iii. audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

6. Payment

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6.1 Institution hereby undertakes that in consideration of Principal Investigator's carrying out Clinical Trial at the Institution in accordance with the terms of this Agreement, Sponsor shall make the payment to the Principal Investigator as per the payment schedule as set forth in Exhibit A. All the payments shall be made directly to the Principal Investigator/designee.

6.2 The Parties agree that the payment of the amount set forth in Exhibit A will be paid by the Sponsor to the Principal Investigator to compensate all the expenses incurred by him in execution and conducting the Clinical Trial at the Institution so that, neither the Study subject, nor the insurance program nor the public assistance agency shall be liable for the same. The payment of the amount set forth in Exhibit A is also meant to compensate Principal Investigator for the professional and clerical allowances, laboratory examinations for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

6.3 Institution and Principal Investigator shall not be entitled to any other expenses, benefits, consideration or fee of co-investigator, whether monetary or otherwise under this Agreement or elsewhere and it covers all out of pocket expenses incurred by Principal Investigator in conducting Study at the Institution including but not limited to telephone, telex, travel and office expenses.

6.4 Sponsor shall be entitled to deduct tax at source (if applicable) while making payment to Principal Investigator on behalf of the Institution under this Agreement.

6.5 In case of very slow/no recruitment, after providing stipulated time of recruitment, at any participating site the competitive recruitment strategy of study subjects would be planned to achieve the overall study timeline based upon the decision taken by the Biological. E (Sponsor). The additional supplement payment towards the additional subject's recruitment will be made by Biological E to the payee as per the same budget calculation and payment schedule.

7. <u>Indemnification and Insurance</u>

7.1 The Sponsor agrees that it shall indemnify, defend and hold harmless the Principal Investigator from and against all suits, claims, losses or damages, arising as a result of (i) either breach of any representation/warranty made by the Sponsor herein and or (ii) of personal injury to (including death of) Study subject, which injury is sustained due to serious adverse events of the Study Drug <u>except</u> to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) Any negligent or wrongful act or omission, or willful malfeasance/ misconduct of the Principal Investigator/ co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

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7.2 It is a condition precedent to the Sponsor's indemnification obligations under above mentioned clause 7.1 that:

a) whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Sponsor of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 7.1 above must (i) promptly notify the Sponsor of the assertion of any such claims (ii) authorize and permit Sponsor to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Sponsor regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Sponsor's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Sponsor in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Sponsor to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Sponsor.

7.3 The Principal Investigator and the Institution hereby irrevocably agree that they shall indemnify and hold harmless the Sponsor, its present and future directors, officers and or employees against any and all consequences, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, cost of fresh studies (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the Institution in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Sponsor by the Principal Investigator and the Institution; or (v) failure of the Principal Investigator and the Institution to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines.

7.4 Insurance

a) The Sponsor undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

b) The Institution undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance coverage from an Indian insurance company for the Study for

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an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

8. **Publication of Results**

It is the general policy of the Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ Institution unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institution request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Sponsor for its perusal, comments and approval. The Sponsor may at its discretion may either refuse the publication or forward it to the Principal Investigator/ Institution along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institution.

9. **Publicity and Product Promoting Activity**

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Sponsor shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Sponsor and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Sponsor.

10. **Confidentiality**

10.1 The Principal Investigator and the Institution agree to keep confidential and secret all materials, documents and confidential information that the Sponsor discloses to the Principal Investigator and the Institution pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the Institution under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Sponsor whether in written, electronic, oral, visual or other form ("**Confidential Information**").

10.2 The Principal Investigator and the Institution agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the Institution shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Sponsor to any third party except as required by law provided that the Principal Investigator and the Institution shall:

(i) first give prompt notice of such disclosure requirement to the Sponsor so as to seek any limitations on or exemptions from such disclosure requirement; and

(ii) reasonably co-operate the Sponsor in any such efforts of defense to be made before appropriate authority.

10.3 Principal Investigator and/or the Institution may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such

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receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the Institution shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the Institution can prove and produces credible written evidence to establish that such information or material:

(a) at the time of disclosure or after disclosure to the Principal Investigator /Institution becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ Institution or their successors or assigns;

(b) by written records were in the Principal Investigator/ Institution's possession at the time of disclosure by the Sponsor were not acquired directly or indirectly from the Sponsor;

(c) subsequent to disclosure hereunder, the Principal Investigator/ Institution receives from a third party legally in a position to provide with information to the Principal Investigator/ Institution, provided, however, that such was not obtained by said third party directly or indirectly from the Sponsor under an obligation of confidentiality.

10.4 All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Sponsor and will be treated as "Confidential Information" by the Principal Investigator and the Institution and may be used by the Sponsor in any manner. Further, Principal Investigator and the Institution shall assign to the Sponsor all of their rights, title, and interest in such Inventions.

10.5 All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Sponsor by Principal Investigator and the Institution forthwith upon written request or upon termination of this Agreement, whichever is earlier.

10.6 Principal Investigator and the Institution agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Sponsor, and that if there is a breach (either actual or threatened) by the Principal Investigator/ Institution or co-investigator or a party in receipt of Confidential Information under this Agreement, the Sponsor would have no complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and Institution agree that the Sponsor shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and Institution shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without

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limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

11. Severability & Waiver and Assignment

11.1 The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement.

11.2 Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof.

11.3 This Agreement shall not be assigned as a whole or in part by Principal Investigator and/or Institution without the prior written consent of the Sponsor.

12. Validity & Termination

12.1 This Agreement shall become effective on the date first set forth above and shall continue for a period of 1 year thereof or until this Agreement is terminated due to:-

a. Determination by the Sponsor that the Principal Investigator is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment;

b. Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Sponsor, to meet at mutually convenient time with the Sponsor enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

c. Determination by the Sponsor that business or scientific considerations require termination;

d. Case report forms provided to the Principal Investigator by the Sponsor to be used in the Study, are not legibly completed and forwarded to the Sponsor or its designated representative;

e. At the request of either DCGI or Ethics Committee;

f. Notification to the Sponsor from central or state regulatory authorities to terminate the Study;

g. Failure of the Principal Investigator/ Institution to provide access by the Sponsor's representatives all original medical records necessary to verify entries on the Study case report forms;

12.2 The Sponsor may terminate this Agreement:

a) At any time upon thirty (30) days written notice to the Principal Investigator/Institution.

b) Immediately for safety reasons relating to the use of the Study Drug.

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12.3 Either Party may terminate this Agreement by notice in writing to the other Party if the other Party commits a breach of this Agreement, and which, in the case of a breach capable of remedy, shall not have been remedied by the defaulting Party within thirty (30) days of receipt of notice identifying the breach and requiring its remedy.

13. Effect of Termination

13.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to complete reports for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

13.2 Upon termination or completion of the Study, the Principal Investigator and Institution shall return to the Sponsor all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/Institution by or on behalf of the Sponsor. In case, the Sponsor desires destruction of aforementioned material, the Principal Investigator/Institution shall destroy such material in front of authorized representative of the Sponsor and shall also provide the Sponsor with a certificate of destruction.

14. Miscellaneous

14.1 It is agreed by the Parties that the Principal Investigator and Institution shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with Sponsor. Neither Principal Investigator nor Institution shall have any authority to represent, or bind the Sponsor.

14.2 Principal Investigator shall comply with all the terms of the Investigator undertaking letter he has provided to the Sponsor.

14.3 This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

14.4 If the terms contained in the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

14.5 The Parties undertake to notify each other of all events that influence the performance of this Agreement. Notifications shall be made to the following addresses:-

(i) **To Sponsor** : Biological E. Ltd.
18/1 & 3, Azamabad
Azamabad, Hyderabad – 500020
Telangana, India

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(ii) **To Principal Investigator:** Dr. NS Mahantshetti
Title: Professor
Address: KLEs JNMC Prabhakar Kore Hospital,
Belgaum, Nehru Nagar, Belagavi, KARNATAKA
Telephone No.: 0674 2304400
Mobile: +91-8312477201
Email id: nsmahantasheeti@gmail.com

(iii) **To Institution:** : Dr. M. V. Jali
Title: Medical Director
Address: KLEs Dr. Prabhakar Kore Hospital &
Medical Research Centre, Nehru Nagar,
Belgaum 590010, Karnataka
Telephone No.: 0831 – 2473777
Fax No: 0831-2470732
Email: drmvjali@gmail.com

Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration in Hyderabad, which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed by the managing director of the Sponsor. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto.

14.6 Parties agree that for claiming injunctive relief and for the enforcement of arbitral award courts in Hyderabad shall have exclusive jurisdiction in all matters arising out of or with this Agreement

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For and on behalf of Biological E Limited	Principal Investigator	For and on behalf of Institution
Signature & Date Name: Mr. Sultan Baig Title: Vice President- Finance Seal: Witness: N.ESWARAREDDY Sr.Vice President - Legal	Signature & Date Name: Dr.N.S. Mahantshetti Title: Professor Dr. N. S. Mahantashetti Professor Consultant Pediatrics KMC Reg. No. 22164 KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi Seal: Witness: Vishal Jakati 29/7/19	Signature & Date 30/07/2019 Name: Dr M.V. Jali Title: Medical Director Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI. Seal: Witness: Revana S Devaninj 30/07/2019

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Exhibit - A

BUDGET AND PAYMENT SCHEDULE

The following budget will apply for the conduct of the ACTIVITY:

Cost Description	Amount (INR)
Investigator, co-investigator & study team fee (INR.8,500 per Subject x 83 subjects)	7,05,500
Study coordinator fee (INR.13,500 per month x 8 months)	1,08,000
Subject travel conveyance (Rs. 500 per subject x 2 visits x 83 subjects)	83,000
Site Logistics, Setup charges (courier, Internet, AV Recording and other etc.)	50,000
Study documents archival fee (for 15 years)	50,000
Sub Total	9,96,500
Institutional Overheads (25% on Investigator fees)	1,76,375
Total	**11,72,875**

Total Cost (in Words): Eleven Lakhs seventy two thousand eight hundred seventy five rupees only. (GST 18% extra as applicable by government laws, wherever applicable)

Budget Note:

- No charges will be paid for screen failure subjects
- TDS will be deducted on all payments as applicable.

The following ACTIVITY linked Payment Schedule will apply for release of total payment to the SITE:

S. No	Payment Milestone	% of Total Cost
1	On Site Initiation	25%
2	On completion of 100% Subject Recruitment	25%
3	After Last Patient/subject Last Visit/Completion of all Data Query Resolutions and Database Lock	25%
4	After Site Close out	25%

Based on the total agreed amount of Rs. 11,72,875/- for enrolling 83 subjects, the per subject cost would be Rs. 9,500/-(Investigator, co-investigator & study team fee + Subject travel conveyance)

All payments would be made based on actual number of subject's enrolled at your site, which would be paid as per the above mentioned budget proposal + GST as applicable.

All study related payments should be made in favour of:

- Payee Name: GDD Experts India Pvt. Ltd.
- Bank Name: AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
- Bank Account Number: 910020034162231,
- IFSC code: UTIB0000048
- GST Registration Number: 27AADCG0363Q1ZA
- PAN of Payee: AADCG0363Q

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA69900906526789R
Certificate Issued Date	:	07-Aug-2019 01:41 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ UTTARHALLI/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0864362121573410R
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	KLE UNIVERSITY JAWAHARLAL NEHRU MEDICAL COLLEGE
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

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CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and among

- **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre**, having a place of business at, Nehru Nagar, Belagavi-590010, Karnataka, India (the "**Institution**"), and
- **Dr. Archana Uppin**, having a place of business at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India. (the "**Investigator**"), and
- **Doclin Clinical Research** Services having a place of business at 445, Maruti Galli, Main Road, Hangarge, Mandoli, Belgavi-590010, Karnataka, 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:	201790
Protocol Title:	A 52-week, phase 3, multicentre, randomised, double blind, efficacy and safety study comparing GSK3196165 withplacebo andwithtofacitinib, in combination with methotrexate in participantswith moderately to severelyactiverheumatoid arthritis who have an inadequate response to methotrexate.
Protocol Date:	22 May 2019
Sponsor:	GlaxoSmithKline Research & Development Limited
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 1.7 "Key Enrollment Date" below)**
IRB/IEC	Name: Institutional Ethics Committee Address: JNMC Campus, Nehru Nagar, Belagavi-590010, Karnataka, India. Ethics Committee Chairperson: Dr. Subarna Roy - +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 GSK (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 GSK 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.

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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.

GSK: means the Sponsor as identified above, GSK's Affiliates or GlaxoSmithKline group of companies, as applicable. Sponsor and GSK's Affiliates are members of the GlaxoSmithKline group of companies.

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.

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.

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 GSK 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 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).

Process(ing): (in reference to Personal Data) any operation or set of operations that is performed upon Personal Data (as defined below), including without limitation collection, recording, retention, alteration, use, disclosure, access, transfer, storage or destruction.

Security Breach: the occurrence of any event that could reasonably be expected to comprise the security of Confidential Information or the security of Personal Data in accordance with Data Protection Legislation (as defined below), or the occurrence of discovering any suspected or actual

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unauthorized disclosure, loss or theft of Confidential Information (as defined below) or Personal Data in accordance with Data Protection Legislation.

RECITALS:
WHEREAS, IQVIA is providing clinical research organisation services to GSK under a separate contract between IQVIA and GSK. IQVIA's 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 IQVIA 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, MCI Regulations, state and local tax and finance regulations and any laws related to protection of medical confidentiality and privacy of personal data. Site and Study Staff acknowledge that IQVIA and GSK, 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 GSK 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 GSK or IQVIA, Site will submit Study Data using the electronic system provided by GSK or IQVIA or their designated representative and in accordance with GSK'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. CRF information associated with a Subject's visit must be satisfactorily completed within seven (7) business days of the Subject's visit, after receipt of Subject's data queries, or if applicable, after receipt of the Subject's test results. Notwithstanding the foregoing, the GSK/IQVIA Study team may communicate in writing the reasonable necessity for response time to be modified (i.e. shortened) during interim analysis, urgent safety review (e.g. dose escalation timing, urgent FDA query) or study closeout periods. For dose escalation, data entry

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and queries must be answered within one (1) business day. The Institution will use reasonable efforts to meet such timing requests and

(iii) retain Medical Records and Study Data for a minimum of fifteen (15) years from the issue date of the clinical study report/summary or equivalent. GSK will inform the Investigator of the date on which the GSK-required retention period will expire. After the expiration of this period, Institution or Investigator is responsible for complying with any remaining relevant local, organizational, state, national and/or regulatory guidelines for records retention. If, at any time during the retention period, Investigator and/or Institution are unable to comply with the record retention responsibilities in this Section (e.g., Investigator retirement; Investigator is no longer employed by or associated with Institution; or, Institution site closure), Investigator or Institution shall transfer responsibility for record retention to another party at the Institution or to a third party off-site archive facility. Investigator or Institution must provide written notice to IAVIA and/or GSK prior to such transfer which specifies the name and address of the new responsible party and, if applicable, the new file location address.

(iv) take measures to prevent accidental or premature destruction or damage of these documents during the retention period. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the GSK. Upon the expiration of the retention period, Site shall comply with any applicable local, organizational, state, national and/or regulatory guidelines for records retention.

If the Investigator leaves the Institution or is otherwise unable to comply with record retention responsibilities, then responsibility for maintaining Medical Records and Study Data shall be transferred to an appropriate responsible party in accordance with applicable regulations and Investigator shall provide written notice to GSK of such transfer. 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 GSK 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 IQVIA and GSK for GSK's use. Site shall afford GSK and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit GSK and IQVIA 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 IQVIA and GSK, 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 IQVIA of, and provide IQVIA 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 IQVIA and GSK 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.

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1.3.4. License. GSK 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 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 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 answer queries related to CRFs submitted within seven (7) business days of the request, except for dose escalation. Investigator must respond to dose escalation queries within one (1) business day.

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 trial-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 GSK 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 GSK and IQVIA.

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 GSK in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

GSK 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.

1.6. Use and Return of Investigational Product and Equipment

GSK or a duly authorized agent of GSK, 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 GSK and according to applicable laws and regulations, including storage in a locked, secured area at all times.

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Upon completion or termination of the Study, the Site shall return or destroy, at GSK's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at GSK'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 IQVIA that are not inconsistent with such laws and regulations.

1.7. Enrollment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective 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 IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" GSK/IQVIA has the right to limit enrollment at any time.

1.9. 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.

1.10. Human Biological Samples

If the Study includes the collection by Site of human biological materials from Study Subjects for research use, Site will comply with all applicable laws, rules, regulations and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Study and with respect to any such human biological materials from the Study retained in Site's possession. Site agrees to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Study and for research use of any human biological materials, with ethics approval. Site agrees that any human biological materials collected as part of the Study that are transferred to GSK or a GSK's contractor, or held by Institution for GSK, will be under the custodianship and control of GSK.

1.11. Human Rights

Respectful of its employees right to freedom of association, Institution represents and warrants, to the best of its knowledge, that in connection with this Agreement, it respects the human rights of its staff and does not employ child labour, forced labour, unsafe working conditions, discrimination of protected characteristic or cruel or abusive disciplinary practices in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the applicable laws on working hours and employment rights in the countries in which it operates. Institution shall be respectful of its employee's right to freedom of association and Institution shall encourage compliance with these standards by any supplier of goods or services that it uses in performing its obligations under this Agreement.

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 IQVIA has received all properly completed CRFs, all data required by the Protocol, including adverse events, and, if IQVIA requests, all other Confidential Information (as defined below).

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Institution and Investigator agree that GSK may make public the amount of funding provided to Institution by IQVIA for the conduct of the Study and may identify Institution and Investigator as part of this disclosure.

3 CONFIDENTIALITY

3.1 Definition

"Confidential Information" means the confidential and proprietary information of GSK and includes (i) all information disclosed by or on behalf of GSK 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 GSK, 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 GSK, 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 GSK, from sources other than GSK that did not have an obligation of confidentiality to GSK;

(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 GSK.

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;

(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 GSK with prompt notice so that GSK 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 GSK at any time, Site shall return to GSK, or destroy, at GSK's option, all Confidential Information other than Study Data.

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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 this Agreement, and no Party or GSK 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 GSK or any of such entity's personnel in performance of the Study. GSK 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 GSK in writing, and Site, on behalf of itself and its personnel, hereby assigns to GSK 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 GSK by executing, and causing its personnel to execute, all documents reasonably necessary for GSK to secure and maintain GSK's ownership rights in Inventions.

4.4 License

GSK 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," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at GSK's request and expense, with GSK'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 Study Transparency and Publication

Before commencement of the Study, GSK will register the Study with a public clinical trials registry. GSK will make public a summary of the Protocol and a summary of the Study results from all Study sites in one or more publicly accessible worldwide registers at any time after the commencement of the Study. GSK will also post the full Study Protocol and statistical analysis plan at the time of results summary posting. Institution and Investigator agree that GSK may make public the names of the Investigator and Institution as part of a list of investigators and institutions conducting the Study when making either protocol or results summary register postings.

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

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any proposed publication or presentation to GSK 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, GSK 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. GSK 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 GSK to seek patent protection for Inventions. The Institution's publication will reference the GSK Publication (as defined below). Institution agrees that GSK's financial support of the Study will be disclosed in any Institution publication. Institution shall ensure that Investigator complies with the obligations identified in this Section 5.

5.2 Multi-Center Publications

GSK will seek to publish the Study results in searchable, peer reviewed scientific literature. The first publication and all subsequent publications of the Study results from all Study sites ("GSK Publication (s)") or disclosure(s) of the Study results, shall be coordinated by GSK. Once the Study is published in a scientific journal, GSK may list the Study on an external website for patient-level data sharing for further research and may also make available the full Study report on the GSK register. If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the GSK'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 GSK's Publication is published; provided, however, that if a GSK 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." Study Subjects' personal information, such as name or initials, shall not be publicly disclosed at any time.

Any participation of Investigator or other representatives of Institution as a named author of this GSK Publication will be determined in accordance with the International Committee of Medical Journal Editors ("ICMJE") Uniform Requirements for Manuscripts, and Institution and Investigator acknowledge that the enrollment of Study Subjects alone is not a qualification for authorship. If the Investigator or other representative of Institution is a named author of the GSK Publication, as an author, he/she (1) will enter into a written author agreement prior to beginning work on the GSK Publication; (2) will have access to the Study data from all Study sites as necessary to fully participate in the development of the GSK Publication; and, (3) will disclose as part of the GSK Publication that GSK financially supported the Study and the GSK Publication, and will disclose any personal financial relationship with GSK. GSK will not compensate authors for authorship activities.

If considered appropriate by GSK, the Investigator or other Institution personnel involved with the Study may participate in the Publication Steering Committee ("PSC") or core writing team(s) for the Study or in public presentations of the Study results. Persons participating as a member of a PSC, in core writing team(s)' activities or in public presentation of the Study results will not receive any payment, honorarium or other fee for participation in such activities nor ownership to nor other title or interest in work product arising out of such activities. However, GSK will reimburse such persons or the Institution (as the case may be and as advised by such persons) for their reasonable travelling and lodging expenses while travelling at GSK's request, provided that travel and lodging expenses have been authorized by GSK in writing in advance and that GSK receives proper original receipts.

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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 GSK. This provision does not prohibit publication or presentation of Study Data in accordance with this Section. Investigator agrees that, if Investigator, consistent with the terms of this Section 5, speaks publicly or publishes any article or letter about a matter related to the Study or Study drug or that otherwise relates to GSK, Investigator will disclose that he/she was an investigator for the Study.

5.5 Use of Name

Except as provided for this Agreement, no Party hereto shall use any other Party's name, or GSK's name, in connection with any advertising, publication or promotion without prior written permission, except that the GSK and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters.

5.6 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6 PERSONAL DATA

6.1 Study Staff 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," as defined in the applicable data protection legislation enacted under the same or equivalent/similar national legislation (collectively "Data Protection Legislation"). This data falls within the scope of the law and regulations relating to the protection of Personal Data and may be used by IQVIA, GSK, and their affiliates in compliance with Data Protection Legislation, including as set forth below and for the length of time reasonably necessary for the purposes below. GSK, IQVIA, and Institution will cooperate with each other to take the necessary measures to ensure adherence to Data Protection Legislation. Institution is responsible for supplying the Investigator and Study Staff with sufficient information regarding the collection of, handling, and use of their Personal Data.

This Personal Data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to financial disclosures or other potential conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

(i) the conduct of clinical trials and/or statistical analysis;
(ii) verification by governmental or regulatory agencies, GSK, 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 or other business; and
(vi) anti-corruption compliance.

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Investigator's and Study Staff's Personal Data may be transferred to countries outside the European Union ("EU"), European Economics Area and Switzerland, such as the USA, which may not provide for the same level of protection as is applicable in Investigator's country. In such event, IQVIA or GSK, as applicable, will make sure that appropriate safeguards are secured in advance of any transfer in accordance with IQVIA's or GSK's, as applicable, legal obligations to ensure the protection of Personal Data according to the Data Protection Legislation.

Names of members of Study Staff may be processed in IQVIA's 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 Processing of data collected in accordance with the Protocol, in compliance with Data Protection Legislation. GSK and Institution agree that, as between them, Institution is best able to manage requests from Study Subjects for access, amendment, transfer, blocking, or deletion of Personal Data. If GSK receives a request from a Study Subject for such access, amendment, transfer, blocking, or deletion, GSK shall forward the request to Institution.

Institution shall respond to Study Subjects' requests for access, amendment, transfer, blocking, or deletion of Personal Data in accordance with Data Protection Legislation and the Agreement. Institution acknowledges that in order to maintain the integrity of Study results, the ability to amend, block, or delete Personal Data may be limited, under Data Protection Legislation.

GSK acknowledges that Study Subjects may withdraw their informed consent to Study participation and consent to Processing of Personal Data at any time as described in the informed consent form signed by the Study Subject. Institution shall promptly notify GSK of any such withdrawal that may affect the use of the Personal Data under the Agreement. Institution will use its best efforts to clarify what the Study Subject's expectations are if the Study Subject withdraws from the Study, including what forms of communication the Institution may use to follow-up with the Study Subject, if any, about their Study Subject's status after withdrawing from the Study.

6.3 Data Protection and Security

GSK and Site shall comply with all applicable laws, including without limitation all applicable Data Protection Legislation relating to the privacy and security of Personal Data and shall implement appropriate technical and organisational measures in such a manner that Processing will meet the requirements of the General Data Protection Regulation ("GDPR") and ensure the protection of the rights of the data subject.

With respect to the coded Study data provided to IQVIA and/or GSK, the Institution and GSK are both considered data controllers for the Processing of the Personal Data and will both act in accordance with Data Protection Legislation.

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 and shall comply with Data Protection Legislation.

Before Processing any Personal Data, Institution and GSK shall ensure, taking into account industry good practice, the costs of implementation and the nature, scope, context and purpose of Processing, as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, that appropriate technical and organisational controls are in place to prevent unauthorised or unlawful Processing of any Personal Data it may hold and to protect any such Personal Data from accidental loss, damage or destruction.

6.4 Security Breaches

i. Notification of Security Breaches. GSK and Institution agree to notify each other without undue delay after of discovery of a Security Breach.
   a. Notice of a Security Breach to GSK, will be sent via e-mail to csir@gsk.com
   b. Notice of a Security Breach to Institution will be sent to [Insert Institution contact information].

ii. In the course of notification to each other, GSK and Institution will provide, as feasible, sufficient information for the parties to jointly assess the Security Breach and make any required notification to any government authority within the timeline required by Data Protection Legislation. Such information may include, but is not necessarily limited to:
   a. The nature of the Security Breach the categories and approximate number of data subjects and records;
   b. The likely consequences of the Security Breach, in so far as consequences are able to be determined; and
   c. Any measures taken to address or mitigate the incident.

iii. GSK and Institution will jointly decide on the basis of all available information and Data Protection Legislation if the Security Breach will be considered a reportable Security Breach and arrange for notification to data subjects and/or government authorities if required by Data Protection Legislation. Where GSK and Institution decide that notification is required by Data Protection Legislation, the party that incurred the Security Breach shall be responsible for providing such notification.

iv. Assistance in Event of Security Breach. In the event of a Security Breach relating to the Personal Data and/or Confidential Information collected or received by a party under this Agreement, the receiving party agrees to assist and fully cooperate with the sending party with any internal investigation or external investigation by third parties, such as law enforcement, through the provision of information, employees, interviews, materials, databases, or any and all other items required to fully investigate and resolve any such incidents and provide information necessary to provide required notifications. The breached party agrees to take such remedial actions as the parties mutually agree is warranted.

v. Neither GSK nor Institution shall disclose, without the other party's prior written approval, any information related to the suspected Security Breach to any third party other than a vendor hired to investigate/mitigate such Security Breach and bound by confidentiality obligations, except as required by applicable laws.Institution agrees to indemnify GSK, for all losses resulting from any Security Breach due to negligence or willful misconduct by Institution, its agents, its Affiliates, or any vendor retained by Institution, including but not limited to legal damages, government penalties, and/or mitigation expenses.

6.5 Survival

This Section 6 "Personal Data" shall survive termination or expiration of this Agreement.

7 INDEMNIFICATION; STUDY SUBJECT INJURY; INSURANCE

7.1. GSK Indemnification

GSK agrees to indemnify, defend, and hold harmless Institution and its affiliates, Investigator, Study Staff, and other Institution employees, agents, and subcontractors ("Institution Indemnitees") from and against any loss, expense, cost (including settlements or ex-gratia payments made with the consent of the parties and reasonable legal and expert fees), liability, damage, or claim by third parties for personal injury, including death, that arises out of the Institution's administration of the investigational medicinal products or procedures provided for by the Protocol or that arises out of the negligence or willful misconduct of GSK ("Institution Claim"), provided that GSK shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

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(i) failure by Institution Indemnitees to conduct the Study in accordance with the Protocol or this Agreement; or

(ii) the negligence or willful misconduct or breach of statutory duty of Institution Indemnitees.

GSK's obligations under this Section with respect to an Institution Claim are conditioned on:

(i) prompt written notification to GSK of the Institution Claim so that GSK's ability to defend or settle the Institution Claim is not prejudiced; and

(ii) Institution Indemnitees' agreement that GSK has full control over the defense or settlement of the Institution Claim and to fully cooperate with GSK in the defense or settlement of the Institution Claim; provided, that, GSK will not settle any such Institution Claim under terms that include an admission of fault or wrongdoing by any Indemnitee or which requires an Indemnitee to undertake a future course of action without that Indemnitee's written consent to such components.

7.2. Study Subject Injury

The Site shall promptly notify IQVIA and GSK in writing of any claim of Study-related injury and cooperate with GSK in the handling of such claim.

If Site provides medical care to a Study Subject to treat a Study-related injury under circumstances described in the approved Study informed consent form as medical expenses for which GSK will pay, GSK will pay Institution directly on the Study Subject's behalf for the care provided. This commitment does not modify GSK's indemnification obligation under this Agreement and is without prejudice to any claim that GSK may have against the Site in the event the Study-related injury was caused by the Site's negligence or failure to follow the Protocol.

7.3. Insurance

Institituion and Investigator confirms that it has sufficient assest or other forms of financial resources to cover for any liability that may arise as out their participation in this Study

This Section 7 "Indemnification; Study Subject Injury; Insurance" shall survive termination or expiration of this Agreement.

8 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 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

9 CONSEQUENTIAL DAMAGES

Neither IQVIA nor GSK shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or GSK for any lost profits, lost opportunities, or other consequential damages.

This Section 9 "Consequential Damages" shall survive termination or expiration of this Agreement.

10 DEBARMENT; DISQUALIFICATION

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

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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.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

11 FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon GSK'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 sub-investigator, 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 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, GSK, 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 GSK'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 for the Study, and that no payments by IQVIA are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products; and, that no payments under this Agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of GSK products. Notwithstanding the foregoing, commercially reasonable payments to a subcontractor who is performing services under the terms of this Agreement that meet the criteria for bona fide services are not considered to be a pass-through rebate or discount payments (even if the subcontractor is a GSK customer).

If the GSK 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 GSK, 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.

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13 ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid by IQVIA pursuant to this Agreement represent bona fide fair market value compensation for the Study-related 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 GSK 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 GSK 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.

Institution represents and warrants that except as disclosed to GSK in writing prior to the commencement of this Agreement: (a) none of their significant shareholders (>25% shareholding) or senior management have influence over GSK's business; (b) no significant shareholders (>25% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services are currently or have been in the past two years, a Government Official with actual or perceived influence which could affect GSK business; (c) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed in the previous clause (b) having a public or private role which involves making decisions which could affect GSK business or providing services or products to, or on behalf of GSK. Institution shall inform GSK in writing at the earliest possible opportunity of any conflict of interest as described in this subsection #13 that arises during the performance of this Agreement.

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 GSK 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 IQVIA and GSK and shall not be considered the employees or agents of IQVIA or GSK.

Neither IQVIA nor GSK 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.

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". IQVIA shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and

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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.

15.2 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 GSK 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, subject enrollment.

16 NOTICE

16.1 Any notices required or permitted to be given hereunder, with the exception of notices given under Section 6.4, Security Breach , 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 GSK:	GlaxoSmithKline Research & Development Limited 980 Great West Road Brentford Middlesex, TW8 9GS United Kingdom
To IQVIA:	**IQVIA RDS (India) Private Limited** III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India and IQVIA Office of the General Counsel P.O. Box 13979 Research Triangle Park,

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	North Carolina 27709-3979 U.S.A. Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com
To Institution:	Name: Dr. Mallikarjun Vamadevappa Jali Address: KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India. Tel: +91-831-2551371
To Investigator:	Name: Dr. Archana Uppin Address: KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India. Tel: +91-9844175418/ 0831-2470400
To Research Company:	Name:Maruti Patil Address: Doclin Clinical Research Services, 445, Maruti Galli, Main Road, Hangarge, Mandoli, Belgavi-590010, Karnataka, India. Tel:+91-9591358733

16.2 Other than as described under Section 6.4, Security Breach , email shall not be a valid method to transmit Notices under this Agreement.

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 IQVIA and GSK.

Upon GSK's request, IQVIA may assign this Agreement to GSK or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after

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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 GSK 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 GSK, 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.

18.7 Binding Authority

IQVIA represents that GSK has granted IQVIA written authority to bind GSK to the GSK obligations expressly included in this Agreement

THIS SECTION IS INTENTIONALLY LEFT BLANK; SIGNATURE PAGE IMMEDIATELY FOLLOWS

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ACKNOWLEDGED AND AGREED BY IQVIA RDS (India) Private Limited:
(formerly Quintiles Research (India) Private Limited)

Name : Tanuka Ganguly

Title : Director, Site and Patient Networks

Signature: Tanuka Ganguly

Date : 26/Sep/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name : Dr. Archana Uppin

Title: Principal Investigator

Signature :

Date : 30/9/19.

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE:

By : Dr. Mallikarjun Vamadevappa Jali

Title: Medical Director and Chief Executive

Signature :

Date : 4/10/19

Doclin Clinical Research Services 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 DOCLIN CLINICAL RESEARCH SERVICES

Name : Maruti Patil

Title (must be authorized to sign on Research Company's behalf): Managing Director

Signature: Patil

Date : 30 Sep 2019

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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	Doclin Clinical Research Services
Payee Address	Doclin Clinical Research Services, 445, Maruti Galli, Main Road, Hangarge, Mandoli, Belgavi-590010, Karnataka, India.
Payee Remittance Email Address	maruti.patil171@gmail.com
Bank Name	Axis Bank
IFSC Code	UTIB0001690
Bank Account Number	919020049795418
GST Number	29AZXPP8818R1ZP
PAN Number	AZXPP8818R
Mode of Payment	Electronic Fund Transfer

The Payee's Tax Identification Number will be required before any payments can be made under this Agreement.

In case of changes in the Payee's address, Site is obliged to inform IQVIA in writing. The parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax- exempt status, 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 DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

C. PAYMENT TERM

IQVIA will pay the Quarterly (January, April, July, October), on a completed visit per 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 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 IQVIA to the Payee upon final acceptance by GSK of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or GSK, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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Major, disqualifying Protocol violations are not payable under this Agreement

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or GSK under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

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 G 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 exclusive of GST. IQVIA will pay to the Payee any amount of GST that the Payee is required to pay in addition to the amounts set out in this Attachment A and in accordance with GST legislation.

D. SCREENING FAILURE

Reimbursement for screen failures will be at the amount indicated on the screening visit of the attached budget, not to exceed one (1) screen failure(s) paid per three (3) subjects 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 subject screening procedures.

E. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

F. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount up to **Eleven Thousand Six Hundred and Seventy Eight Indian Rupees** (11678 **INR** [which includes overhead]), as denoted in the Budget Table. 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.

G. INVOICES

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: QBAN Finance Department
Address: III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur- Marathahalli, Outer Ring Road,
Bangalore- 560103, India

Phone: +91 -080 71315909

Please note that invoices will not be processed unless they reference the GSK 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.

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- **Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments**

IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of invoice and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by IQVIA and GSK, will be reimbursed upon receipt of invoice.

- **Record Storage Fee/Archiving Fee** – a record retention payment of **Ninety Thousand Indian Rupees (90,000INR)** will be paid upon receipt of invoice and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain at Site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

H. BUDGET TABLE

VISIT	TOTAL AMOUNT (OVERHEAD INCLUDED)
SC	36986.4
BL W0	25148.4
W1	17270.4
W2	22060.8
W3	5948.4
W4	19183.2
W5	5948.4
W6	5948.4
W7	5948.4
W8	19183.2
W9	5948.4
W10	5948.4
W11	5948.4
W12	31566
W13	22882.8
W14	5948.4
W15	3475.2
W16	22602
W17	3475.2
W18	5948.4
W19	3475.2
W20	6489.6
W21	3475.2
W22	5948.4
W23	3475.2
W24	28497.6
W25	3475.2
W26	5948.4
W27	3475.2
W28	6489.6
W29	3475.2
W30	5948.4
W31	3475.2
W32	6489.6
W33	3475.2
W34	5948.4
W35	3475.2
W36	22602
W37	3475.2

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W38	3475.2
W39	3475.2
W40	6489.6
W41	3475.2
W42	3475.2
W43	3475.2
W44	6489.6
W45	3475.2
W46	3475.2
W47	3475.2
W48	13503.6
W49	3475.2
W50	3475.2
W51	9288
EoT W52	29572.8
TOTAL COST PER SUBJECT (INCLUDING OVERHEAD)	**506578.8**

OTHER VISITS	TOTAL AMOUNT (OVERHEAD INCLUDED)
Safety Follow Up Visit (SFU)	17901
Re-Screening Visit (Re-SC)	29628
Unscheduled Visit (UV)	11678

PD and Biomarkers Sub- study

VISIT	TOTAL AMOUNT (OVERHEAD INCLUDED)
BL W0	1032
W1	1032
W2	1032
W4	1032
W12	1032
W24	1032
Total Additional Cost Per Patient under PD and Biomarker sub study (including Overhead)	6192

I. CONDITIONAL PROCEDURES (WITH INVOICE)

The following conditional procedure costs will be reimbursed on a pass-through basis upon receipt of an original invoice in the amount indicated in the table below (which includes overhead). Subject number and visit dates must be included on the invoice for payment to be issued.

Procedure	Total (OVERHEAD INCLUDED)
Re-consent, Informed consent performed again with the same patient	1,404
Partner pregnancy Informed consent	859
Genomics consent; DNA consent; Genetics	859
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative	360
High Resolution Computed Tomography (HRCT), thorax, chest, lung for interpretation and report use R1255; (CT Scan)	31,225
Interpretation and Report; High Resolution Computed Tomography	9,163
Telephone assessment and management service provided by a qualified nonphysician health care professional to an	1,104

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established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	
Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy	1,560
Physician: Pulmonary Medicine - Per Hour	4,652
Serious adverse events (SAE)	2,828
Patient Reimbursement, Expenses, Patient Travel - Per Visit	913
Meal Reimbursement- Per Visit	795

J. MINIMUM ENROLMENT GOAL

Site acknowledges that Site's minimum enrollment goal is **75** 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.

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ATTACHMENT B

The Site will be supplied with a Lenovo Tablet; the model number is YB1-X90L. The cost of the tablet is USD 439 (Four Hundred and Thirty Nine US dollars).

All materials and equipment provided ("Equipment") by the GSK or IQVIA/vendors contracted by the GSK shall remain the sole property of the GSK/IQVIA/vendor, as the case may be.

Therefore, it is hereby agreed that such Equipment shall:
a) be subject to removal at any time upon the GSK's or, IQVIA' demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;

b) be used only for the purposes of the Study;

c) be used in accordance with any manuals or instructions while in possession of the Site;

d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;

e) be clearly identified as the sole property of the GSK/IQVIA/vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and

f) upon completion or termination of the Study, IQVIA or GSK, together with Site assistance, shall arrange the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the GSK or IQVIA in writing, arrange for the disposal of the Equipment as soon as reasonably practicable

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED UNLESS APPROVED BY IQVIA AND GSK

Except for GST, these amounts include all applicable taxes.

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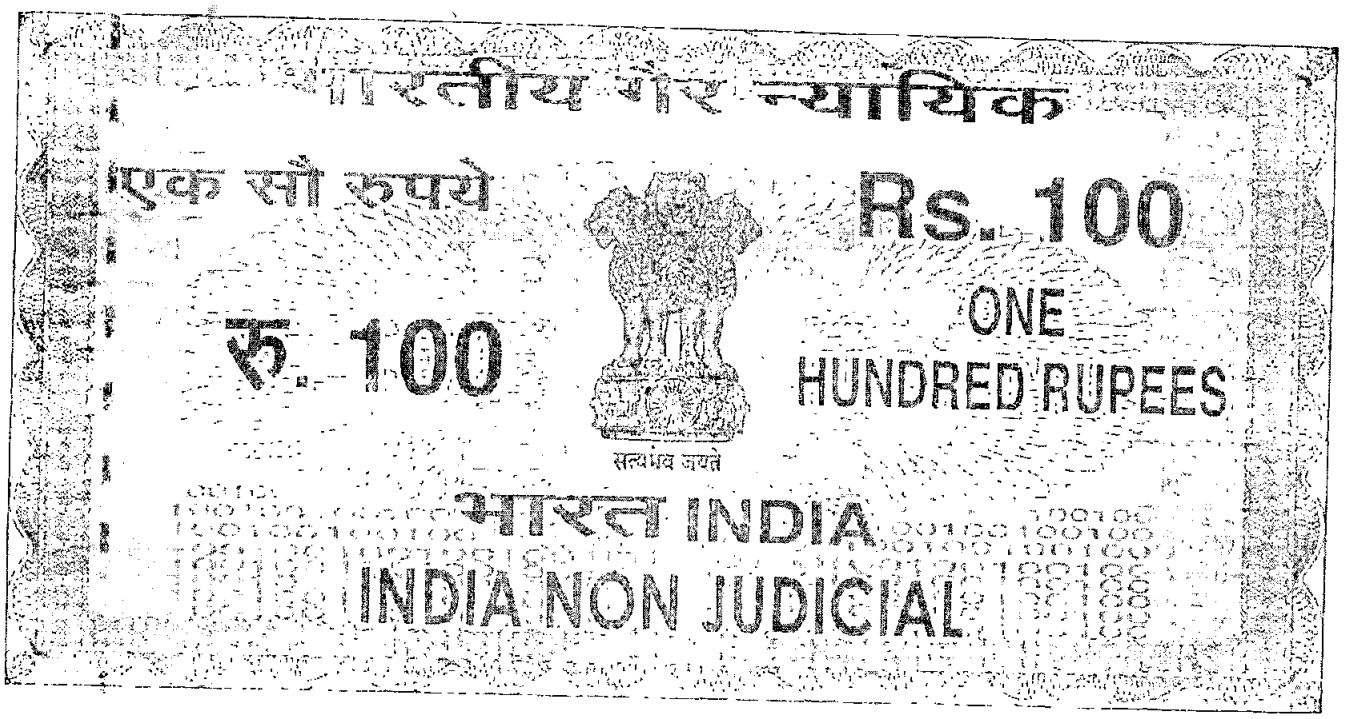

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ VP 609520

प्रधान मुद्रांक कार्यालय, मुंबई
१६ AUG 2019
सक्षम अधिकारी
श्री. वि. के. गवई

PRODUCT CODE:	SSR29263
STUDY CODE:	LPS14914
STUDY NAME:	KIDDIE

INVESTIGATOR/INSTITUTION CONTRACT

Site Name: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Belgavi

Study Code / Name: LPS14914/KIDDIE **Effective date:** 16th October 2019

Initials SPONSOR Initials INSTITUTION ATTESTED Initials INVESTIGATOR Initials SMO

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Registrar
KLE Academy of Higher Education
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This Contract (hereinafter "the Contract") is made on this **7th day of November 2019,** by and among:

DOCTOR MAHANTESH V. PATIL having his address at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belguam-590010, Karnataka, India

Hereinafter the "**INVESTIGATOR**",

AND

KLEs DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESERCH CENTRE having its address Nehru Nagar, Belguam-590010, Karnataka, India represented for the purposes hereof by Dr. M. V Jali, Medical Director

Hereinafter the "**INSTITUTION**"

AND

GDD EXPERTS INDIA PRIVATE LIMITED having its address at Ground floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur – 440001, Maharashtra, India represented for the purposes hereof by Mr. Vinod Gyanchandani, Head Clinical Operations

Hereinafter the "**SMO**",

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, CSU Cluster Head, India-South East Asia

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION, the SMO and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a ~~clinical~~ **A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children** (hereinafter the « Study ») to evaluate Sanofi drug **Enterogermina® /Bacillus clausii /SSR29263** (hereafter the «Investigational Medicinal Product») in accordance with a protocol entitled **KIDDIE/LPS14914** and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care;

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Pediatrics, and

WHEREAS, the SMO is a site management organization which specializes in providing the services of clinical research coordinators, management of funds of the INSTITUTION at the clinical studies/trials sites and has accordingly provided the SPONSOR a certificate, a copy of which is attached hereto as "**Annexure 1**", and

WHEREAS, the SPONSOR shall have no liability whatsoever arising out of selection and appointment of SMO and payments made to the SMO, including but not limited to any claims, demands, actions, causes of action, judgments, damages, expenses and costs, including attorney's fees, which arise out of, result from, occur during or are connected in any

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manner with the Study or any related activities or Investigator meetings, irrespective of whether or not they are sponsored, supervised or controlled by the SPONSOR, except such liability arising directly and solely from gross negligence on the part of the SPONSOR, and

WHEREAS, the INSTITUTION, the INVESTIGATOR and the SMO having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

WHEREAS, the **"Subject"** means an individual who is selected in accordance with the terms of the Protocol to participate in the Study.

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION/SMO shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/ Regulatory Authority («RA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/RA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belguam-590010, Karnataka, India, (hereafter the **«Study Site»**). The INVESTIGATOR and the SMO shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION and/or the SMO include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term **«Collaborators»** shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as well as

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participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR.

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH – GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR, the INSTITUTION and the SMO shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

3.4 The INVESTIGATOR, the INSTITUTION and the SMO shall submit CRF/eCRFs to the SPONSOR. If needed, the SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a computer and/or internet connection in order to submit eCRFs for the Study. The INVESTIGATOR and any Collaborator (as such term is defined at Article 2) will be trained by the SPONSOR with respect to the use of eCRFs. Before the training process, the INVESTIGATOR, each Collaborator and the representative of the INSTITUTION/the SMO shall acknowledge statements of understanding and acceptance of their obligations regarding the eCRF process.

ARTICLE 4. TERM.

This Contract is being entered into force from **16th October 2019 ("the Effective Date")** and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take 13 (thirteen) months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR, the INSTITUTION and the SMO with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators, the SMO and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or a third party's account.

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5.3 The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.4 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/RA/CA.

5.5 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION and/or the SMO under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.6 The INVESTIGATOR, the INSTITUTION and the SMO or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION/SMO shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.7 The INVESTIGATOR/INSTITUTION and the SMO agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.8 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION and the SMO by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **85 (Eighty Five)** Subjects, within **12 (Twelve)** months. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study Site. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the Study Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study Site.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the Informed Consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any Subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

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7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the Informed Consent Form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR, the INSTITUTION and the SMO to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR, the INSTITUTION and the SMO agree to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR, the INSTITUTION and/or the SMO shall immediately inform the SPONSOR of any Serious Adverse Event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR, the INSTITUTION and the SMO of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION and/or the SMO in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's Brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR, the INSTITUTION and the SMO agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use.

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The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR/ INSTITUTION/SMO; (2) is disclosed to the INVESTIGATOR/INSTITUTION/SMO by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR/INSTITUTION/SMO prior to disclosure under this Contract, as shown by the INVESTIGATOR'/INSTITUTION's/SMO's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR/INSTITUTION/SMO gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy file containing the essential documents related to the Study and records generated during the Study (**"Study File"**) for the longest of the two following periods (**the «Retention Period»**):

- Twenty-five (25) years after the signature of the final Study report or,
- Such longer period as required by applicable regulatory requirements.

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION/the SMO during this period.

If during the Retention Period, the INSTITUTION/the SMO is no longer able to retain the Study File due to exceptional circumstances (such as bankruptcy), the INSTITUTION/the SMO shall contact the SPONSOR to organize the transfer of the Study File to the SPONSOR at the SPONSOR's expense.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION and/or the SMO will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Regulatory Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

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ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR, the INSTITUTION and the SMO undertake not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION, the SMO, and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION, the SMO and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

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(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including

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the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice ("GCP") and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / the SMO/ PAYEE shall permit inspections, investigations and audits by or on behalf of the SPONSOR subject to the provisions below, and inspections by any health or regulatory authority, including, but not limited to, European Medicines Agency and U.S. Food and Drug Administration ("Regulatory Authorities"). The INVESTIGATOR and the INSTITUTION/ the SMO/PAYEE shall prepare for the abovementioned investigations, audits and inspections in cases where they are informed in advance, and shall make their best efforts to facilitate their conduct.

17.2 The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.3 The INVESTIGATOR, the INSTITUTION and the SMO shall devote their best efforts to facilitate the performance of any audit, investigations and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.4 As soon as the INVESTIGATOR, the INSTITUTION and/or the SMO is notified of an inspection by any Authorities which is related to the Study or may affect its conduct, they shall, to the extent permitted by applicable regulations or the relevant Regulatory Authorities (i) promptly inform the SPONSOR of the inspection (ii) prepare for such inspections in collaboration with the SPONSOR (iii) provide in advance the SPONSOR, for review and comment, with any draft of written answer to a question of an Authority, (iv) authorize the SPONSOR to participate to the aforementioned inspections, (v) provide the SPONSOR with a copy of any and all documents given to, sent or collected by the Authorities in the framework of said inspections, and (vi) provide the SPONSOR with any reports, result or analyses issued by the Regulatory Authorities in the framework of said inspections.

17.5 The INVESTIGATOR, the INSTITUTION and the SMO shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits, investigations or inspections.

17.6 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR/INSTITUTION/SMO for the audits, investigations and inspections and that the assistance and availability of the INVESTIGATOR/INSTITUTION/SMO for the audits, investigations and inspections is included in the amount mentioned in Exhibit 1.

17.7 The rights and obligations under this Article shall remain in effect for **25 (Twenty Five)** years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR/the INSTITUTION and the SMO upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION and/or the SMO for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment

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provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

18.3 The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither the INVESTIGATOR/INSTITUTION/SMO nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION/SMO has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

19.2 The INVESTIGATOR and/or the INSTITUTION and/or the SMO shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR, the INSTITUTION and the SMO shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

20.2 In the interest of transparency relating to the SPONSOR's financial relationships with the INVESTIGATOR/INSTITUTION/SMO, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION/SMO and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

(a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and

(b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that they have not accepted nor been offered any payment of money or other assets, or anything of value, for the purpose of influencing their decisions or actions to help the SPONSOR obtain or maintain business or obtain a business advantage where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by "Anti-Bribery Provisions").

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21.2 The INVESTIGATOR, the INSTITUTION and the SMO further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable Anti-Bribery Provisions.

ARTICLE 22. MISCELLANEOUS.

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION and/or the SMO under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

22.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR, the INSTITUTION and the SMO shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

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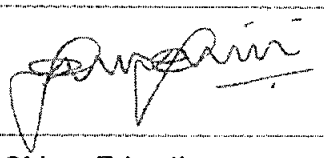
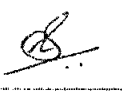
22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in four counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		**INVESTIGATOR**	
[Signature]		**[Signature]**	
[Name]	**Dr. Chirag Trivedi**	**[Name]**	**Dr. Mahantesh V. Patil**
[Title]	**CSU Cluster Head, India-South East Asia**	**[Title]**	**Principal Investigator**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	**S. S. Parab**	**[Name]**	Shruti H

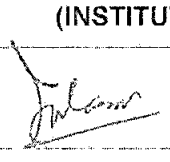
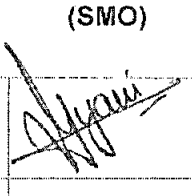
KLEs DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE (INSTITUTION)		**GDD EXPERTS INDIA PRIVATE LIMITED (SMO)**	
[Signature]		**[Signature]**	
[Name]	**Dr. M. V Jali**	**[Name]**	**Dr. Vinod Gyanchandani**
[Title]	**Medical Director**	**[Title]**	**Head Clinical Operations**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	Revana Soevaintri	**[Name]**	Rajani Asundi

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EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 16th October 2019

1) The SPONSOR will pay **INR.1,00,000/- (Rupees One Lakh only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

   Such amount is divided as follows:

Visits	Visit no.	Per visit cost (INR) (A)	Hospitalization (5 days) (INR) (B)	Patient reimbursement (INR)	Total (INR)
V1/ Screening/ Baseline visit Day 1	V 1	19,000	1,000	1000	21,000
Day 2	V 2	13,000	1,000		14,000
Day 3	V 3	13,000	1,000		14,000
Day 4	V 4	13,000	1,000		14,000
EOT/ Day 5	V 5	15,000	1,000	1000	17,000
EOS/ Day 6	V 6	19,000	-	1000	20,000
		92,000	**5, 000**	**3,000**	**100,000**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost will be INR 1,000/- per visit as the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

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Local lab cost workings:

Parameters	Price (INR)
Hemoglobin Hematocrit Red blood cell [RBC] count Morphology [if RBC count is abnormal] White blood cell [WBC] WBC differential Neutrophils Lymphocytes Monocytes Eosinophils Basophils Platelet count Absolute neutrophil count [ANC]	1190
Blood Chemistry Sodium Potassium Chloride Bicarbonate Blood urea nitrogen (BUN) Creatinine Creatinine clearance Calcium Phosphate Total protein Albumin	950
C-reactive protein	2200

3) For screen failure, the SPONSOR will pay INR 2,000/- (Rupees Two Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid on actuals to payee, upon receipt of a valid invoice issued on letterhead of payee and receipt by Sponsor.

5) 25% Institutional overheads on aforesaid Point 1 (except Subject reimbursement)

6) Monthly admin charges of INR 2,000/- (Rupees Two thousand only) per month will be paid towards stationary, internet, fax, courier and telephone charges from SIV till Study site close out visit.

7) A onetime start-up fee of INR. 75,000/- (Rupees Seventy Five thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

8) Sponsor will pay INR 165 (Rupees One Hundred and Sixty Five only) per box per month after the Study Closure to PAYEE for archival and document storage for a period of 25 years from the date of site closure

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9) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

10) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

11) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the PAYEE against presentation by the PAYEE of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the PAYEE shall indemnify the SPONSOR such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the PAYEE on *Quarterly* basis upon presentation of the invoices in Indian Rupees by a bank wire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

Bank Name & Branch:	AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
Bank IFSC	UTIB0000048
Account No.:	910020034162231
PAYEE:	GDD EXPERTS (INDIA) PVT.LTD.
PAN No.:	AADCG0363Q
GST No.:	27AADCG0363Q1ZA

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all Discrepancy Resolution Form/ electronic-Discrepancy Resolution Form "DRF/e-DRF" and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

ATTESTED

Prof. Dr. V.A.KOTHIWALE
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<SMO letterhead>

Annexure 1

TO WHOMSOEVER IT MAY CONCERN

THIS IS TO CERTIFY that GDD Experts India Private Limited is responsible for Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management of Acharya Vinoba Bhave Rural Hospital, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha- 442004, Maharashtra, India. All clinical responsibilities towards patient care has been accordingly subcontracted to GDD Experts India Private Limited who is responsible for such activities on a non-profit basis.

All Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management related money shall be credited to "GDD Experts India Private Limited" as per following details:

Bank Name & Branch:	AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
Bank IFSC	UTIB0000048
Account No.:	910020034162231
PAYEE:	GDD EXPERTS (INDIA) PVT.LTD.
PAN No.:	AADCG0363Q
GST No.:	27AADCG0363Q1ZA

ACKNOWLEDGED AND AGREED BY GDD EXPERTS:

Name: Dr. Vinod Gyanchandani

Signature: _____

Date: 19/Nov/2019

Place of Issue. Nagpur

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-KA34506370229744R
Certificate Issued Date	:	07-Nov-2019 11:54 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM30/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL08873276591722O4R
Purchased by	:	DR MAHESH KALLOLI
Description of Document	:	Article 5(J) Agreement (In any other cases)
Property Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KLES Dr PRABHAKAR KORE HOSPITAL AND MRC BELAGAVI
Second Party	:	DR MAHESH KALLOLI
Stamp Duty Paid By	:	DR MAHESH KALLOLI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Issued by
The Judicial Employees
Co-operative Credit Society Ltd.
Dist. Court Complex, Belagavi
Pooja
Authorised Signatory

Please write or type below this line

TO,

THE MD & CE,

KLE'S DR.PRABHAKAR KORE HOSPITAL & MRC,

NEHRU NAGAR, BELAGAVI-590010

SUBJECT: UNDERTAKING REGARDING HANDLING OF FINANCES FROM THE CLINICAL TRIALS AND RESEARCH PROJECT BY DR. MAHESH KALLOLI

ATTESTED

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

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CLINICAL TRIAL AGREEMENT

Among

1. CADILA HEALTHCARE LIMITED, , a multinational pharmaceutical company incorporated under the laws of India, having its Registered Office at Cadila Healthcare Limited a company incorporated under laws of India, having its registered office at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat, India (hereinafter referred to as **"the Sponsor")**

2. **DR. MAHESHKUMAR VEERANNA KALLOLI KLE'S DR PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE** (hereinafter referred to as **"Principal Investigator")**

3. **KLE'S DR PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE NEHRU NAGAR, BELGAVI-590010, INDIA** (hereinafter referred to as **"the Institution")**

CADILA PROJECT:

A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients" (Project No._TDM1.17.001)

This Clinical Study Agreement ("Agreement") is executed on **01-Nov-2019** ("Effective Date") among Cadila Healthcare Limited, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat, India; Dr. Maheshkumar Veeranna Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre Nehru Nagar, Belgavi-590010, India, for the study entitled A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2-Positive Metastatic Breast Cancer Patients" (Project No._TDM1.17.001)" (Hereinafter referred to as **"the study").**

This Agreement also covers any companion protocol(s) later developed and approved by all the Parties that are conducted concurrently with the protocol identified herein (collectively "Protocol") and that involve some or all the same subjects. The Sponsor and the Institution hereby declare that all the necessary permissions and licences required under the provisions of various acts and rules thereunder have been obtained for the performance of their respective obligations under this Agreement.

AND WHEREAS the Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study.

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

THE PARTIES AGREE AS FOLLOWS:

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1 The Sponsor would like to test the biosimilar namely Trastuzumab Emtansine (TDM1) which will be used in patients with metastatic breast cancer aged 18 to 65 years at the time of enrollment in the study. The Sponsor hereby declares that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely Drugs & Cosmetics Act, 1940 and Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) will be obtained before the start of the study.

2 The Sponsors have approached the Investigator as they desire to perform the study in regards to the said drug in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices and Local Regulations and have accordingly finalized the Clinical Trial Protocol.

3 The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled "A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients" (Project No._TDM1.17.001)". All amendments and appendices have also been read and understood. The investigator agrees to the protocol and will perform the study in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices, and applicable laws, rules and regulations.

THE PARTIES AGREE AS FOLLOWS:

4 **Investigators and Research Staff**

4.1 **Principal Investigator:** The Study will be conducted by Dr. Maheshkumar Veeranna Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre Nehru Nagar, Belgavi- 590010, India,with registration number **71566**; the Principal Investigator. The Principal Investigator hereby confirms that he is a competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub-investigators and research staff and the Institution.

4.2 **Sub-investigators and Research Staff:** Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub-investigators or research staff.

4.3 **Obligations:** Principal Investigator will ensure that all 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. Principal Investigator is responsible to the Sponsor for compliance by Investigators, with the terms of this Agreement.

4.4 **No Substitution:** The Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from the Sponsor.

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4.5 **Delegation of Duties by Principal Investigator:** The Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical trials in India.

4.6 **Compliance with Institutional Policies:** The Principal Investigator will comply with the policies and procedures of the organization/institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify the Sponsor promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation

4.7 **Audit:** The Principal Investigator will make necessary arrangement for inspection of documents etc. by Sponsor's monitor, official of regulatory agency.

5 **Funding:** The conduct of the study will not impose any financial burden on the Principal Investigator or the Institution. The Sponsor declares to bear all the expenses pertaining to the conduct of the study.

5.1 **Financial Support for Clinical Trial:** The details of the financial support to investigators and the budget sheet are attached in Annexure A hereunder:

6 **Protocol:** Investigator will conduct the Study in accordance with the Protocol, Indian GCP guidelines and applicable rules and regulations in India.

6.1 **Amendments:** The Protocol may be modified only by a written Amendment, signed by both the Sponsor and the Principal Investigator.

6.2 **Emergency Amendments:** If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Investigator will notify the Sponsor and the responsible Independent Ethics Committee or Institutional Review Board (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by execution of a written Amendment within 30 days.

6.3 **No Additional Research:** No additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.

7 **Subject Enrolment:** Investigator has agreed agrees to enrol the subjects in the study as may be defined and decided by the Sponsor from time to time. A qualified subject is one who meets all Protocol criteria such as inclusion & exclusion criteria and agrees to participate in the study through informed consent in writing.

7.1 **Excess Enrolment:** If Investigator enrols the maximum number of qualified subjects, the Sponsor may or may not invite Investigator to enroll additional subjects. However, the Principal Investigator shall not enroll more than maximum number without prior approval by the Sponsor.

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7.2 Failure to Enroll: If Investigator fails to enroll subjects at a rate adequate to meet the enrollment requirement, the SPONSOR shall be free to terminate the Study early (see Section 23, Termination).

8 Study Conduct: Investigator will conduct Study in accordance with the Protocol, the Sponsor's written instructions, Indian Good Clinical Practices (Indian GCP) guidelines and all applicable governmental laws, rules, and regulations.

8.1 No Charge for Investigational Drug or Reimbursed Services: Investigator will not charge a Study subject or third-party payer for Investigational Drug (see Section 13, Investigational Drug) or for any services reimbursed by the Sponsor under this Agreement.

9 Independent Ethics Committee/Institutional Review Board: Before the Study is initiated, Investigator will ensure that both the Study and the informed consent form are approved by an Independent Ethics Committee or Institutional Review Board (as applicable) (both referred to as a 'IRB') that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct.

10 Study Disapproval: If, through no fault of Investigator, the Study is disapproved by the IRB, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 23.1.a, Disapproval by IRB, below.

11 Data Protection: Data collected in Study may include personal data and sensitive information which is subject to specific legislation relating to the processing, storage, transfer and use of such data or information. The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Cadila Healthcare Limited group of companies, to representatives and contractors working on behalf of the Sponsor group and to regulatory authorities across the world. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause 11. The Principal Investigator shall be responsible for obtaining Sponsor's permission before publication or conference presentation of any Sponsors' data.

12 Informed Consent and Authorization to Use and Disclose Health Information

12.1 Informed Consent: Investigator will obtain a written informed consent from each Study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow the Sponsor to inspect signed informed consent forms or photocopies thereof during monitoring visits or audits (see Monitoring and Audits, Section 16).

13. Adverse Events: Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone, e-mail or facsimile. The Investigator shall, so far as is lawful, have full responsibility for the reporting of all serious and unexpected adverse events and/ or deaths to local regulatory authorities as per prevailing regulations. The Sponsor has and will maintain during the Study, an insurance policy adequate to cover adverse events or injury to Study Subject(s) as a direct result of participation in the Study. . Investigational Drug: The Sponsor will provide Investigator with sufficient quantities of the investigational drug(s) needed to conduct the Study.

13.1 Custody and Dispensing: The Principal Investigator will maintain appropriate control of supplies of Investigational Drug and will not provide it to anyone else except sub-investigators or research staff. The Principal Investigator shall maintain the records of inventory of the Investigational drug.

13.2 Use: Investigator will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Agreement.

13.3 Ownership of Investigational drug: Investigational drug remains the property of the Sponsor except for, and limited to, the use specified in the Protocol, the Sponsor grants Investigator no express or implied intellectual property rights in Investigational drug or in any methods of making or using the Sponsor's DRUG.

14. Confidential Information: During the course of the Study, Investigator may receive or generate information that is confidential to the Sponsor. Any information marked by the sponsor as confidential and provided to the investigator 1 year before the execution of this agreement will also be treated as confidential information.

14.1 Definition: Except as specified in Section 14.2, Exclusions, below, "Confidential Information" includes

a. the Protocol,
b. the Investigator Brochure,
c. Study Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), subject to Investigator's right to publish the results of the Study (as described in Section 18, Publications, below),
d. Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), and
e. Any other information related to the Study, the Sponsor's DRUG, or The Sponsor technology, research, or business plans that THE SPONSOR provides to Investigator in writing or other tangible form and marks as CONFIDENTIAL and then summarizes and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure.

14.2 Exclusions: Confidential Information does not include information that

a. is known or open to the public or otherwise in the public domain at the time of disclosure,
b. becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Investigator,
c. is already known to Investigator at the time of disclosure and is free of any obligations of confidentiality, or

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d. Is obtained by Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

14.3 **Obligations of Confidentiality:** Unless the Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the IRB or to regulatory representatives is specifically authorized.
b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 18, Publications, of this Agreement.

14.4 **Disclosure Required by Law:** If disclosure of Confidential Information to any party other than the IRB relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator

a. Notifies the Sponsor in writing in 15 working days advance of the disclosure so as to allow the Sponsor to take legal action to protect its Confidential Information,
b. Discloses only that Confidential Information required to comply with the legal requirement, and
c. Continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 **Individually Identifiable Health Information**: If, in connection with this Study or performance of this Agreement, the Sponsor comes into contact with individuality identifiable health information relating to subjects who are not Study subjects, the Sponsor agrees to maintain the confidentiality of such information and not to use it for any purpose.

14.6 **Survival of Obligations:** These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the study and marketing of the drug.

14.7 **Return of Confidential Information:** If requested by the Sponsor in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. **Study Data, Biological Samples and Study Records:**

15.1 **Study Data:** During the course of the Study, Investigator will collect and submit certain data to the Sponsor or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical images, ECG, or other types of tracings or printouts, data summaries, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data to the Sponsor or its agent within the reasonable time period.

a. **Ownership of Study Data:** Subject to Investigator's right to publish the results of the Study (see Section 18, Publications), the Sponsor is the exclusive owner of all Study Data.

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b. **Non-exclusive License:** The Sponsor grants Investigator no right to use study data for any purpose including internal research and/or education purpose.
c. **Data Management and statistical Analysis:** The Sponsor or its representative shall carry out the data management and statistical analysis. The Sponsor may consult and / or provide the Principal Investigator for interpretation during report writing.
d. THE SPONSOR is the exclusive owner of study data.

15.2 **Biological Samples:** If so specified in the Protocol, Investigator may collect and provide to the Sponsor or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study subjects for testing that is directly related to subject care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

a. **Use:** Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.
b. **Analysis samples:** The Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, the Sponsor will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator or Study subject.
c. **Ownership:** The Sponsor is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

15.3 **Study Records:** Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a. **Retention:** Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of 5 years after termination of the Study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify the Sponsor before destroying any Study Records after the required retention period. Investigator further agrees to permit the Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16. Monitoring, Inspections and Audits

16.1 **Monitoring:** The Sponsor shall be entitled at its absolute discretion (and in such form as the Sponsor sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit the Sponsor representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by the Sponsor will relieve the Investigator of any of its obligations hereunder.

16.2 **Inspections and Audits:** The Study is subject to inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. The Sponsor may also choose to audit Study Records as part of its monitoring of Study conduct.

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a. **Notification:** Investigator will notify the Sponsor as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.
b. **Cooperation:** Investigator will cooperate with regulatory agency or the Sponsor representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.
c. **Resolution of Discrepancies:** Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.
d. **Inspection Findings and Responses:** Investigator will promptly forward to the Sponsor copies of any inspection findings that Investigator receives from a regulatory, agency. Whenever feasible, Investigator will also provide. The Sponsor with an opportunity to prospectively review and comment on any Investigator responses to regulatory agency inspections.
e. **Data Clarification Form:** The Sponsor may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the Principal Investigator or his nominee shall clarify within 7 working days.
f. **Study Conduct Evaluations:** The Sponsor or its external service providers may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor will use these evaluations solely for internal purposes.

17. **Inventions:**

17.1 **Notification:** If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the SPONSOR

17.2 **Assignment:** Investigator will assign all interest in any such Invention to the Sponsor, free of any obligation or consideration beyond that provided for in this Agreement.

17.3 **Assistance:** Investigator will provide reasonable assistance to the SPONSOR in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

18. **Publications:**

18.1 **Prepublication Review:** The Sponsor has no objection to publication by Investigator of any information collected or generated by Investigator, whether or not the results are favourable to the Investigational Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, Investigator will provide the Sponsor, an opportunity to review any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. The timing of such publication shall be mutually agreed upon.
a. **Submission to the Sponsor:** Investigator will provide manuscripts, abstracts, or the full text of any other intended disclosure (poster presentation, invited speaker or guest lecturer presentation, etc.) to the Sponsor at least 90 days before they are submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Investigator agrees to delay the disclosure for a period not to exceed an additional 360 days.
b. **Redaction of Confidential Information:** Investigator will, on request, remove any previously undisclosed Confidential Information (other than the Study results themselves) before disclosure.

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19. **Debarment and Exclusion:** The Principal Investigator and Investigator each certify that it/s/he / she is not debarred and that it/s/he/she is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Investigator and Principal Investigator will notify the SPONSOR promptly if either of these certifications needs to be amended in light of new information.

20. **Use of Name:** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify the Principal Investigator and Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

21. **Assignment and Delegation**

21.1 The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the Sponsor. Any attempt to so assign, delegate, or subcontract is invalid. If the Sponsor authorizes delegation or subcontracting, Institution remains responsible to the Sponsor for the performance of all delegated duties.

21.2 The Sponsor may not assign its rights or delegate its duties under this Agreement without written permission from the Principal Investigator. Any attempt to so assign or delegate is invalid. However, the SPONSOR may freely subcontract Study-related duties to an external provider upon advance notice to the Principal Investigator, and also may freely assign its rights or delegate its duties to any of the Sponsor affiliate. If the SPONSOR delegates or subcontracts any duties, the Sponsor remains responsible to the Principal Investigator for the performance of those duties.\

21.3 **Affiliates:** As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with the Sponsor

21.4 **Successors and Assigns:** This Agreement will bind and inure to the benefit of the successors arid permitted assigns of each party.

22. **Conflict with Attachments:** If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

23. **Indemnity:** Each Party upon receipt of prompt notice and opportunity to defend, shall indemnify and hold the other party harmless, and hereby forever releases and discharges the other Party from and against claims, demands, liabilities, damages and expenses including attorney fees arising out of the negligence of the indemnifying Party in connection with the work performed under this Agreement, provided, however, each party shall not be obligated to indemnify, defend or hold harmless the indemnified party to the extent the claim is caused by gross negligence or willful misconduct of that party.

24. **Term and Termination:**

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24.1 Termination Conditions: This Agreement terminates upon the earlier of any of, the following events:

a. **Disapproval by IRB:** If, through no fault of Investigator, the Study is never initiated because of IRB disapproval, this Agreement will terminate immediately.

b. **Study Completion:** For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by the Sponsor of all Protocol-required data and Biological Samples; and receipt of all payments due to either party.

c. **Termination Upon Notice:** The SPONSOR reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

d. **Immediate Termination by the Sponsor:** The Sponsor further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the Sponsor 's opinion pose risks to the health or well-being of Study subjects; or regulatory agency actions relating to the Study or the Investigational Drug.

e. **Termination Upon Notice by Investigator:** The Principal Investigator may terminate the study, if the Sponsor does not comply with the agreement related to finance, supply of medication for the study and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to the SPONSOR fifteen days prior to termination and the Sponsor shall have fifteen days to cure its default.\

f. **Immediate Termination by Investigator:** Investigator reserves the right to terminate the Study immediately upon notification to the SPONSOR if requested to do so by the responsible IRB or if such termination is required to protect the health of Study subjects.

24.2 Payment upon Termination: If the Study is terminated early in accordance with Section 23.1 Termination Conditions, above, the Sponsor will provide a termination payment equal to the amount owed for work already performed, less' payments already made. If the Study was never initiated because of disapproval by the IRB (see Section 23.1.a, Disapproval by IRB, above), the Sponsor will reimburse Investigator for IRB fees and for any other expenses that were prospectively approved, in writing, by the Sponsor

24.3 Return of Materials: Unless the Sponsor instructs otherwise in writing, Investigator will promptly return all materials supplied by the Sponsor for Study conduct, including unused Investigational Drug, unused Case Report Forms, other study related material and any the Sponsor - supplied Equipment.

24.3.1 Electronics Items: On completion of the clinical study, the Investigator will return all the electronic items & their accessories in the working condition (if any) as provided by the Sponsor during the study.

24.4 Treatment Code (Blinded Studies Only): Upon request, the Sponsor will provide Investigator with a treatment assignment list that identifies, by subject number, the treatment that each Study subject received. Unless otherwise specified in the Protocol, the Sponsor will provide such treatment assignment information only after the Study is completed (or has been terminated and all data submitted) at all participating sites.

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24.5 **Survival of Obligations:** Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, and Debarment and Exclusion survive termination of this Agreement as does any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

25. **Modification:** Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.

26. **Entire Agreement:** This Agreement and any Exhibits and Attachments and the Indemnity at Exhibit represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

27. This agreement shall be interpreted and enforced under the laws of India and the Courts of Ahmedabad shall have exclusive jurisdiction to resolve any dispute under this Agreement.

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Executed by the parties:

SPONSOR:

(Mr. Mukund Thakkar)	(Dr. Sanjay Maroo)
SVP-Legal	GM, Clinical R&D

PRINCIPAL INVESTIGATOR: Dr. MaheshKumar Veeranna Kalloli

Sign: _____

INSTITUTION: KLE'S Dr. Prabhakar Kore Hospital and MRC
Dr Mallikarjun Vamadevappa Jali
Designation: Medical Director and Chief Executive

Sign: _____

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub-investigators and research staff are informed of their obligations under this Agreement.

Sign: _____

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Annexure A:

Budget Sheet and other expenses:

Investigational drug		Trastuzumab emtansine		Clinical trial phase		III
Investigators & Center		Dr. Mahesh Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre				
Protocol title/number(s)		A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients: TDM1.17.001				
Budget:		Rate per patients	No. of patients	No. of visit	Total cost	Maximum payable amount
Investigators' Professional Fees:						
	Screening	13000	1	1	13000	103000
	Enrollment visit without PK	10000	1	1	10000	
	Follow up visits (cycle 2-8 and End of study visit)	10000	1	8	80000	
Patients reimbursement:						
	Screening	1000	1	1	1000	10000
	Enrollment visit	1000	1	1	1000	
	Follow up visits (cycle 2-5 and End of study visit)	1000	1	8	8000	
Study co-ordinator:						
	Screening	4000	1	1	4000	26500
	Enrollment visit without PK	2500	1	1	2500	
	Follow up visits (cycle 2-5 and End of study visit)	2500	1	8	20000	
Phlebotomist:						
	Screening	500	1	1	500	5000
	Enrollment visit without PK	500	1	1	500	
	Follow up visits (cycle 2-5 and End of study visit)	500	1	8	4000	
Radio Diagnostic Tests						
	Screening (contrast CT_Chest, abdomen with pelvis)	14000	1	1	14000	47000
	*Enrolled (CT scan-Contrast-Chest and Abdomen with Pelvis)	14000	1	2	28000	
	Bone scan	5000	1	1	5000	

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	Special Clinical Examination (2D ECHO)					
	Screening	2000	1	1	2000	2000
	Special Clinical Examination (Chest X-Ray)					
	Screening	450	1	1	450	450
	Special Clinical Examination (ECG)					
	Screening	300	1	1	300	2700
	*Enrolled	300	1	8	2400	
	Hospitalization charges:					
	Enrolled	3500	1	8	28000	28000
	Administration costs:					
	Phone/fax calls					2000
	Couriers/Xerox					
	Drug Storage					
	Institutional Overhead (25%)- only PI and CRC					32375
	Total				226650	259025
Note	(1) Maximum amount paid per completed patient without PK will Rs.				259025	
	(2) First installment is for ethics committee fees(As per actual).					
	(3) Reimbursement of all expenses against monthly invoices with supporting vouchers (if required).					
	(4) Final payments made will be only on the basis of subjects completed in the trial. Cost of screen failures is adjusted in the payments for the enrolled subjects as per the above projections.					
	(5) Payments will not be done for wrongly enrolled subjects.					
	(6) Of the total eligible payment,70% will be paid while the study is on-going at regular intervals, 20% will be paid after completion of data management and remaining 10 % on signing of the clinical study report.					
	(7) Upto 10% of the drop-outs in the study will be reimbursed as per the actual expenses. Drop-out above 10 % will not be reimbursed.					
	(8) Tax deduction at source (TDS)/GST as per the applicable regulations. GST as per applicable rules.					
	(9) Archival charges of INR 42,000 will be paid extra to archive study documents for 15 years.					
	(10) No monthly payments will be processed if no patients are enrolled within two months from date of study was conducted at site					
	(11) Local pathology/pharmacy/any other investigations charges as per actuals.					
	(13) Payee details: Payee name: MG CLINICAL RESEARCH Payee address: sector no 12, Plot no 17, M M Nagar, Jain bhasti, Karnataka-590018, Belgaum Bank name: HDFC BANK Bank account name: MG CLINICAL RESEARCH Bank account number: 50200044101301 IFSC code: HDFC0000253					

ATTESTED

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

Clinical Trial Agreement

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Engaged by:

Intas Pharmaceuticals Ltd.,
Plot No: 423/P/A,
Sarkhej-Bavla Highway,
Moraiya, Sanand,
Ahmedabad,
Gujarat, India 382213.
(Hereinafter referred to as the "Sponsor")

AND

KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Institution" or "Site")

AND

Dr. Maheshkumar Kalloli
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Investigator")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA")

Intas Pharmaceuticals Ltd.,
Plot No: 423/P/A,
Sarkhej-Bavla Highway,
Moraiya, Sanand,
Ahmedabad,
Gujarat, India 382213.
(Hereinafter referred to as the "Sponsor")

AND

"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
"ICH GCP"	ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"SAE"	Serious Adverse Event as defined by ICH GCP.
"Site"	The site at which the Clinical Trial is conducted.
"Study"	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.

2 **Investigator/Institution responsibilities**

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, New Drugs and Clinical Trials Rules, 2019, and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members 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 Investigator is responsible for notifying LAMBDA of such change in a timely manner.

this Agreement to the contrary, the 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 deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambdaundertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3 **CRO responsibilities**

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Electronic Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

6.2 However following matters shall survive even after expiry/termination of the agreement:

- Archival of study documents including source data as referred to in para 2.7 (i) and Section III/k on page # 24.
- Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
- Confidentiality as per para 11

7 **Data ownership / Intellectual property rights**

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

ATTESTED

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

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11 **Confidentiality**

11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) is already in the public domain at the time of disclosure

b) becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) was previously known to the Institution or the Investigator as evidenced by written documents

14 **Termination**

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

1. Investigator or Institution fails to recruit patients within **60** days of site initiation visit.
2. The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.
3. Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.
4. LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.
5. The total number of patients required to be randomised is reached before the end of the recruitment period.
6. The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.
7. The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA.

15 **Record retention**

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, New Drugs and Clinical Trials Rules, 2019 and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO 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. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.

15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least 15 (Fifteen) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

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

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Telephone : +918312470400
Fax : +918312493099

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19 **Miscellaneous**

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

19.6 "All the Invoices raised to Lambda (CRO) should be GST compliant, according to the GST Invoice rules. Absence of necessary detail will result in delay /non-payment of Invoices till the time of rectification made."

ATTESTED

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

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Principal Investigator:

Sign: _____ **Date:** 05/NOV/2019

Dr. Maheshkumar Kalloli
Principal Investigator
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India

Witness:

Sign: _____ **Date:** 05 Nov 2019

Witness Name : D Deepak

Witness Address : KLES Prabhakar Kore Hospital & MRC

ATTESTED

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

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Schedule B: Budget and Payment Agreement (I) Budget

Protocol Number: 0566-18		INVESTIGATOR GRANT (For Three Weekly Regimen)									
	Visit No.	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Total
	Cycle No.	NA	1	2	3	4	5	6	NA	NA	
	Weeks	Wk -2 to 0	0	3	6	9	12	15	18	24	
1	Investigator Grant	8500	8000	8000	9000	8000	9000	8000	10500	11000	80000
2	Co-ordinator Grant	3000	1500	1500	2000	1500	2000	1500	1500	3000	17500
3	Day Care Charges		3000	3000	3000	3000	3000	3000			18000
4.1	ECG (12 Lead)	400	400	400	400	400	400	400	400	400	3600
4.2	ECHO	2000					2000			2000	6000
4.3	CT/MRI scan (Whole Body) - Contrast / Bone Scan[5] (if applicable)	17000			17000		17000		17000		68000
4.4	Hepatitis (HCV and HepB) and HIV Screen	LTR Central Lab									0
4.5	Serum Pregnancy Test (For Female Subjects	LTR Central Lab							450	LTR Central Lab	450
4.6	Urine Pregnancy Test (For Female Subjects)		200	200	200	200	200	200			1200
4.7	Biochemistry and Urinalysis[1, 6]	LTR Central Lab			4000		4000			LTR Central Lab	8000
4.8	Hematology[1] - at Local Lab	500	500	500	500	500	500	500	500	500	4500
4.9	Biochemistry[2] - at Local Lab		800	800		800		800	800		4000
	Total	31400	14400	14400	36100	14400	38100	14400	31150	16900	211250
5	Institutional Overhead (25%) - Applicable on Investigator Grant and Coordinator Grant	2875	2375	2375	2750	2375	2750	2375	3000	3500	24375
	Total (with Institutional Overhead at 25%)	34275	16775	16775	38850	16775	40850	16775	34150	20400	235625
6	Patient Compensation (on actuals)	500	500	500	500	500	500	500	500	500	4500
	Total Grant/patient										240125

Note:

1	Hematology: Hemoglobin, hematocrit, WBC count with differential (as percentage for white blood cells and absolute for neutrophils & eosinophils only) RBC count and platelet count. BioChemistry: Total protein, albumin, alkaline phosphatase, GGT, AST, ALT, total bilirubin, triglycerides, cholesterol, glucose, calcium, phosphorous, potassium, sodium, urea, creatinine, eGFR and uric acid. Urinalysis: Specific gravity, pH, semi-quantitative evaluation of glucose, protein, bilirubin, ketones, leukocytes, blood. A microscopic examination including RBC, WBC, and casts
2	BioChemistry: ALT,AST, ALP, Total Bilirubin & Serum Creatinine
3	Patient compensation will be provided based on actual bills only (provided is upper limit)
4	Archival would happen at Lambda Clinical Services facility.
5	If Bone Scan will be performed as per PI discretion, only INR 5000/- per bone scan will be paid.
6	Biochemistry and Urinalysis at visit 4 and visit 6 will be performed at Local Lab

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

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LAMBDA will release payment within 30 days from the receipt of invoice.

k) Archival would happen at Lambda Clinical Services facility.

Should the trial terminate prematurely, any payments made by LAMBDA exceeding the amount actually earned will be promptly refunded to LAMBDA (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

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 Institution & PI. Details of Payee are:

Payment through Cheque:	
Name of Payee:	**MG CLINICAL RESEARCH**
Address of Payee:	**sector no 12, Plot no 17, M M Nagar, Jain bhasti, Belgaum, Karnataka,590018**
PAN / TAN Number:	**ABFPG5340M**
Payment through wire transfer:	
Name of Beneficiary Account:	**MG CLINICAL RESEARCH**
Beneficiary's Account Number:	**50200044101301**
Bank Name:	**HDFC BANK**
Bank Address:	4830 / 28A, DrAmbedkar Rd, Belgaum, Karnataka,**590002**
IFSC:	**HDFC0000253**
GST Number:	**29ABFPG5340M1ZG**

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. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) **Per Patient Fee, Payment Schedule and Terms**

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the Trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" 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 eCRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like Hb level measurement etc.)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses for safety samples
- usage of internet while filling of eCRF
- Patient conveyance/compensation which will be on a pro rata basis
- miscellaneous (telephone, fax, courier, etc.)

- All overhead costs.

Not included are (which are separate and in addition to per patient payment):
- EC submission fee

2. In the event that the LAMBDA requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the LAMBDA under this Agreement will be done within 30 days following receipt of the corresponding invoice from the Investigator to LAMBDA, it being understood that such payment will only take place after the CRO (LAMBDA) has received the necessary funds for that purpose from the Sponsor. All such payments will be Any made by A/C Payee Cheques to the Institution/Investigator.

4. Payment mentioned under "safety follow up" will be released at the time of site close out. The Final Payment will be made by LAMBDA in accordance with the following paragraphs.

5. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA. These additional tasks will be submitted to LAMBDA in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA and are subject to prior written approval by LAMBDA, which, in its turn, must obtain prior written approval from Sponsor.

6. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, LAMBDA has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to LAMBDA any amount by which amounts advanced by the CRO exceed the adjusted Trial Cost.

7. The CRO may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation:
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

8. Sponsor reserve right to verify study related payment records (e.g. invoices , patient reimbursement receipts) at SITE or at LAMBDA as applicable ; as a compliance measure .

9. **Screen Failures**: All screen failure patients payments will be made post LPLV. Reimbursement for screen failures will be at the amount indicated on the screening visit of the schedule-B budget, not to exceed One (1) screen failure(s) paid to four (4) Subject(s) randomized.Reimbursement for discontinued or early termination Subjects will be prorated based on the number of confirmed completed visits.

10. For any disputed payments from the invoices, site will communicate through proper channel of LAMBDA.

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Prof. Dr. V.A.KOTHIWALE
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LAMBDA will pay a sum **Rs. 2, 40, 125/- (Two Lakh Forty Thousand One Hundred Twenty Five Rupees Only) for Three Weekly regimen** for every complete and evaluable Subject as defined in the payment schedule.

The above budget also includes the

a. Investigator (s), other team members fees
b. The cost which would be incurred for stationary, cupboard, courier, telephone, fax, internet and electricity bills etc.
c. Patient recruitment
d. e-Case Report Form completion
e. Data Clarification Form Resolution
f. Consultation charges

(I) **Payment Schedule**

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) 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 completely and accurately

b) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

c) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and e-CRF review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

d) Any other parties designated by you (including Radiology, Local Laboratory, Cardiology, etc.) will be managed and paid by you.

e) The **Ethics Committee fees** will be paid by LAMBDA on behalf of the Sponsor, and it is separate from per patient grant as mentioned in budget.

f) For Screen failure patients, the payment will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, SAE, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before randomization will be paid for screening day.

g) 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.

h) Patient conveyance/compensation will be paid by LAMBDA on behalf of the Sponsor, and is included in budget as mentioned. "TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." GST applicable as per union budget rules.

i) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

j) Payment mentioned under "Final Payment" will be released at the time of site close out.

ATTESTED

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

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Schedule A

Study Protocol

Protocol No: 0566-18

"A MULTICENTRIC, OPEN LABLE, SINGLE ARM STUDY TO EVALUATE THE SAFETY AND EFFICACY OF INTP26 (TRASTUZUMAB BIOSIMILAR) IN PATIENTS WITH HER2 – OVEREXPRESSING BREAST (EARLY OR METASTATIC) CANCER OR METASTATIC GASTRIC CANCER".

N WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: _____ Date: 2/Nov/2019

Mr. Rajiv Bhattacharya / Mr. Gautam Vaghela
Clinical Trial Management,
Lambda Therapeutics Research Ltd.

Witness:

Sign: _____ Date: 02/Nov/19

Mr. Naresh Khemani
AGM, Finance,
Lambda Therapeutic Research Ltd.

Witness Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad 380061, Gujarat

Institute: KLES Dr. Prabhakar Kore Hospital and MRC

Sign: _____ **Date:** 06/11/19

Name: Dr M.V. Jali
Designation: MD and CE
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India

Investigator: Dr Mahesh Kalloli

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

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15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than **30** days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16 **Representation and Warranty**

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17 **Laws and Jurisdiction**

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18 **Notice**

18.1 All notices shall be delivered to the following addresses:

CRO	:	**Lambda Therapeutic Research Ltd**
Address:	:	Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Ahmedabad-382481, Gujarat, India.
Telephone	:	+91 79 4020 2020
Fax	:	+91 79 4020 2021
Contact Person	:	**Dr. Kiran Marthak**
Institution	:	KLES Dr. Prabhakar Kore Hospital and MRC
Address	:	KLES Dr. Prabhakar Kore Hospital and MRC Second Floor, SMO, Nehru Nagar, Belagavi – 590010, Karnataka, India
Telephone	:	+918312470400
Fax		+918312493099
Investigator	:	**Dr. Maheshkumar Kalloli**
Address	:	KLES Dr. PrabhakarKore Hospital and MRC Second Floor, SMO, Nehru Nagar, Belagavi – 590010, Karnataka, India

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d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12 **Privacy**

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13 **Independent Contractor**

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

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7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and thisagreement, irrespective of the PI presence in the institution. Institution will allowregulatory authorities, sponsor and CRO to perform inspections of study data. In casethe PI has to leave the institution, the PI should handover charge of the study to anyother designee in form of document and forward all future communications received toinstitute pertaining to trial. PI is responsible to update CRO and / or sponsor for thischange and all applicable communications, henceforth. Designee will execute all PIresponsibilities, henceforth. In case of change in institution management, the institutewill inform CRO and / or sponsor

8 Publication

8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9 Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 Sponsor will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

10 Compensation / Insurance

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.

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3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4 **Performance standards of the work to be conducted by the Investigator**

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **01-02 patient** within **1 months**; minimum expected recruitment rate from the site is **01-02 patients** per month on an average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be **6** months as per study design; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within **3** working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, New Drugs and Clinical Trials Rules, 2019 and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5 **Payment terms**

5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B. Lambda will have oversight on patient reimbursement records maintain at the site.

6 **Period of validity of the Agreement**

2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.7 During the performance of the Clinical Trial and for a period of 15 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not 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 LAMBDA on a regular basis;

c) ensuring direct access by Lambda monitors, Lambda auditors, Sponsor representative and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) to allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda'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.

i) Archival of study documents including source data/patient medical records in accordance with ICH-GCP for at least 15 years after completion of study as per the site archival fees which will be paid by sponsor on actual.

2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor, Ethics Committee, Head of institution, DCGI and Expert Committee (In case of Death). The 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. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in

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KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Institution" or "Site")

AND

Dr. Maheshkumar Kalloli
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Investigator")

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of Intas Pharmaceuticals Limited.

Intas Pharmaceuticals Limited has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled "**A multicentric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar) in patients with HER2-overexpressing breast (early or metastatic) cancer or metastatic gastric cancer.**" ("Clinical Trial") to be conducted under the direction and supervision of the Investigator using the facilities of the Institution; and,

The Investigator and Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1 **Definitions**

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	INTP26 – Trastuzumab Biosimilar 150mg/vial and 440mg/vial of Intas Pharmaceuticals Limited, India
"CRF"	Case Report Form
"CRO"	Contract/Clinical Research Organization
"Declaration of Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA41795185066833R
Certificate Issued Date	:	01-Jul-2016 05:09 PM
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Unique Doc. Reference	:	SUBIN-KAKAKSFCL08103686694584498R
Purchased by	:	IQVIA RDS INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PVT LTD
Second Party	:	KLES DR PRABHAKAR KORE HOSPITAL AND M R C
Stamp Duty Paid By	:	IQVIA RDS INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

UTTARHALLI SOUHARDA CREDIT CO-OPERATIVE LTD. 3393/2015-16

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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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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. Rohan Bhise**, 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 Private Limited**, having a place of business at Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India (the "**Research Company**")
- **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:	SAMSON-II
Protocol Title:	A Randomized, Double-blind, Parallel Group, Equivalence, Multicenter Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-squamous Non-small Cell Lung Cancer. **EudraCT no.:** 2017-005175-78
Protocol Date:	Version 1.0 – 22 April 2019
Sponsor:	Prestige BioPharma Pte Ltd
Country where Site is Conducting Study	India
Investigator:	Dr. Rohan Bhise
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	Name: Institutional Ethics Committee, KLE University Address: KLE University, JMNC Campus, Nehru Nagar, Belagavi - 590010, Karnataka, India. Chairperson Name: Dr. Subarna Roy Chairperson contact number: +91 9449033133

The following additional definitions shall apply to this Agreement:

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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 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).

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RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA's 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 IQVIA 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, 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.

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 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 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

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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 IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and IQVIA 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 IQVIA 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 IQVIA of, and provide IQVIA 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 IQVIA 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 (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 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.

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

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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 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.

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 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.

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 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. Equipment provided to Site for the Study, if any, is listed on Attachment C hereto. 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.

1.7. Enrollment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrollment Date

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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 15 "Term & Termination" Sponsor/IQVIA has the right to limit enrollment at any time.

1.9. 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.

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 IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below).

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;

(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;

(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.

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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 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," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

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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. 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 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

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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 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 and may be used by IQVIA, Sponsor, and their affliates in compliance with applicable law, including as set forth below and for the length of time reasonably necessary for the purpose below.

For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to financial dislocures or other potential conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

(i) the conduct of clinical trials and/or statistical analysis;
(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 or other business and;
(vi) anti-corruption compliance.

Investigator's personal data may be transferred to countries outside of Investigator's country, which may not provide for the same level of protection as is applicable in Investigator's country. In such event, IQVIA or Sponsor, as applicable, will make sure that appropriate safeguards are secured in advance of any transfer in accordance with IQVIA's or Sponsor's, as applicable, legal obligations to ensure the protection of Investigator's personal data according to the data protection laws and regulations applicable in Investigator's country.

Names of members of Study Staff may be processed in IQVIA's 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 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.

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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.

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 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, regulation or guidance, including GCPs, issued by any regulatory authority, or
(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. 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 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

9. 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.

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

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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.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

11. 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 sub-investigator, 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 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, 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 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 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.

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,

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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.

14. 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.

t 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.

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". 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.

15.2 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

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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, 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:	Prestige BioPharma Pte Ltd 2 Science Park Drive, Ascent Tower B, #04-13/14, Singapore 118222 Phone : +65-6924 6535 Fax : +65-6924 2053
To IQVIA	**IQVIA RDS (India) Private Limited** III Floor, Etamin Block,Prestige Technology Park, Sarjapur - Marathahalli Outer Ring RoadBangalore – 560103, Karnataka, India Tel: +91 8071317778 and IQVIA Inc. Global Legal Department 100 IMS Drive Parsippany, NJ 07054 USA Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com
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. Rohan Bhise

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	Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: +91 8312470400
To Research Company	Name: Dr. Vinod Gyanchandani Address: GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Apartment, 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 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.

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

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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

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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: 26/July/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Rohan Bhise

Title: Principal Investigator

Signature: Rohan

Date: 29-July 2019

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE:

By: Dr. M. V. Jali

Title : Medical Director

Signature: 14 Aug 2019

Date: _____

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: 22/Aug/2019

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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	Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
Payee Phone and E-Mail address	Phone Number: +91 9923000560 Email ID: vgyanchandani@gddexperts.com
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

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 **quarterly**, on a completed visit per 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 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 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.

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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 3 (three) 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 subjects will be prorated based on the number of confirmed completed visits.

F. SCREENING FAILURE

Reimbursement for all screen failures will be made at the amount indicated on the screening visit of the attached Budget.

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 subject screening procedures.

G. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of is **Twelve Thousand Seven Hundred Fifty Nine Indian Rupees (INR 12,759)**. 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.

H. INVOICES

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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: Finance PSC – Accounts Payable (Investigator Payments)
Address: III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India
Phone: +91 8071317779

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number, Investigator name, Site number and Payee GST registration number. Upon receipt and verification of the invoices, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

- CONDITIONAL PROCEDURES:

Payment for conditional procedures performed out of a visit, may be reimbursed including overhead upon receipt of original invoice. Invoice must reference date when the procedure was performed, list of procedures, and subject numbers.

Conditional Procedure	Amount/Currency
Re-consent, Informed consent performed again with the same patient	INR 1,400
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (**HD204/EU-Avastin**); initial, up to 1 hour	INR 4,300
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (**Carboplatin/Paclitaxel**); initial, up to 1 hour	INR 4,300
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (**Carboplatin/Paclitaxel**); each additional hour	INR 2,000
Pharmacy, Complex (**Carboplatin/Paclitaxel**) - Per Preparation; dispense drug	INR 1,693
Immunogenicity sampling - ADA/NADA - central lab	INR 350
Lab handling and/or shipping to central lab	INR 300
Haematology: Haemoglobin, white blood cell (WBC), Platelets and absolute Neutrophil count	INR 800
Blood chemistry panel: alanine aminotransferase (ALT/SGPT), Alkaline Phosphatase, total Bilirubin, Serum or Plasma creatinine, sodium, Potassium, Total calcium, BUN or Urea, Albumin	INR 1,800
Blood chemistry panel: Magnesium (Mg)	INR 600
Coagulation panel: International Normalized Ratio (INR)	INR 1,000
Coagulation panel: Thromboplastin time, partial (PTT) (aPTT);	INR 900
Urinalysis	INR 500
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative	INR 900

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Serum pregnancy, gonadotropin chorionic (hCG) (BetahCG); quantitative	INR 1,800
12 lead ECG: Includes tracing, interpretation and report	INR 1,390
Meal (Patient) - Per Meal	INR 609
Meal (Caregiver) - Per Meal	INR 609
Patient Reimbursement, Expenses, Patient Travel - Per Visit	INR 1,179
Caregiver Reimbursement, Expenses, Caregiver Travel - Per Visit	INR 1,179
Patient Reimbursement, Stipend - Per Visit	INR 2,180
Caregiver Reimbursement, Stipend - Per Visit	INR 2,180
Daily Facility Charge - Per Day, for Study Infusion Visits only	INR 2,294
Tumor Assessment (RECIST 1.1)	INR 2,106
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	INR 20,000
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	INR 5,000
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material; can be used for peripheral artery tomography	INR 17,000
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	INR 4,800
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); with contrast material(s)	INR 40,636
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); with contrast material(s)	INR 6,723
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	INR 14,456
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	INR 4,094
Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); with contrast material(s)	INR 13,475
Interpretation and Report; Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); with contrast material(s)	INR 3,631
Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); without contrast material	INR 11,667
Interpretation and Report; Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); without contrast material	INR 3,286

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Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen, pelvis combined (Cat Scan) (CT Scan); with contrast material	INR 33,826
Interpretation and Report; Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen and pelvis(Cat Scan) (CT Scan); with contrast material	INR 4,191
Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen, pelvis combined (Cat Scan) (CT Scan); without contrast material	INR 30,610
Interpretation and Report; Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen and pelvis(Cat Scan) (CT Scan); without contrast material	INR 4,247
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	INR 16,300
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	INR 5,000
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	INR 14,000
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	INR 14000
Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	INR 56790
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	INR 7578
Magnetic resonance imaging, chest, thorax, thoracic (MRI); without contrast material(s) (eg, proton)	INR 42368
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); without contrast material(s) (eg, proton)	INR 6597
Magnetic resonance imaging, abdomen, abdominal (MRI); with contrast material(s) (eg, proton)	INR 51367
Interpretation and Report; Magnetic resonance imaging, abdomen, abdominal (MRI); with contrast material(s) (eg, proton)	INR 6650
Magnetic resonance imaging, abdomen, abdominal (MRI); without contrast material(s) (eg, proton)	INR 38147
Interpretation and Report; Magnetic resonance imaging, abdomen, abdominal (MRI); without contrast material(s) (eg, proton)	INR 5797
Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton)	INR 41730

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Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton)	INR 5343
Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	INR 46768
Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	INR 6205
Magnetic resonance imaging, pelvis, pelvic (MRI); without contrast material(s), followed by contrast material(s) and further sections (eg, proton)	INR 53115
Interpretation and Report; Magnetic resonance imaging, pelvis, pelvic (MRI); without contrast material(s), followed by contrast material(s) and further sections (eg, proton)	INR 8023
Magnetic resonance imaging, liver, pancreas (MRI); without contrast material(s)	INR 49712
Interpretation and Report; Magnetic resonance imaging, liver, pancreas (MRI); without contrast material(s)	INR 8931
Bone and/or joint imaging, bone scan, bone scintigraphy, limited area	INR 16,800
Interpretation and Report; Bone and/or joint imaging, bone scan, bone scintigraphy, limited area	INR 3,400
Radiologic examination, chest; single view	INR 1000
Interpretation and Report: Radiologic examination, chest; single view	INR 490
Serious adverse events (SAE)	INR 2800

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.

Start-up Fee

A one-time, non-refundable payment will be paid in the amount of Eighty Thousand Indian Rupees (INR 80,000) to cover Study start-up activities upon completion and receipt by IQVIA of all original contractual and regulatory documentation and receipt of an original invoice.

Archiving Fee

A one-time record storage payment will be paid in the amount of Fifty Thousand Indian Rupees (INR 50,000) 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.

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NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

These amounts exclude all applicable taxes.

All payments for this Study in accordance with the attached budget will be paid by IQVIA by wire transfer.

BUDGET TABLE

Visits	Amount/Currency
Screening Visit	Rs 40,104
Cycle 1	Rs 37,296
Cycle 2	Rs 38,002
Cycle 3	Rs 34,143
Cycle 4	Rs 38,359
Cycle 5	Rs 24,128
Cycle 6	Rs 27,987
Cycle 7	Rs 24,128
Cycle 8	Rs 24,128
Cycle 9	Rs 24,128
Cycle 10	Rs 26,623
Cycle 11	Rs 24,128
Cycle 12	Rs 24,128
Cycle 13	Rs 24,128
Cycle 14	Rs 26,623
Cycle 15	Rs 24,128
Cycle 16	Rs 24,128
Cycle 17	Rs 24,128
EoT	Rs 31,423
Total amount per subject	Rs 541,840
Safety Follow-Up Visit (not included in Total)	Rs 4,550
Dosing after 12 months (not included in Total)	Rs 23,426

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ATTACHMENT B
APPROVAL LETTER

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ATTACHMENT C
EQUIPMENT *(optional)*

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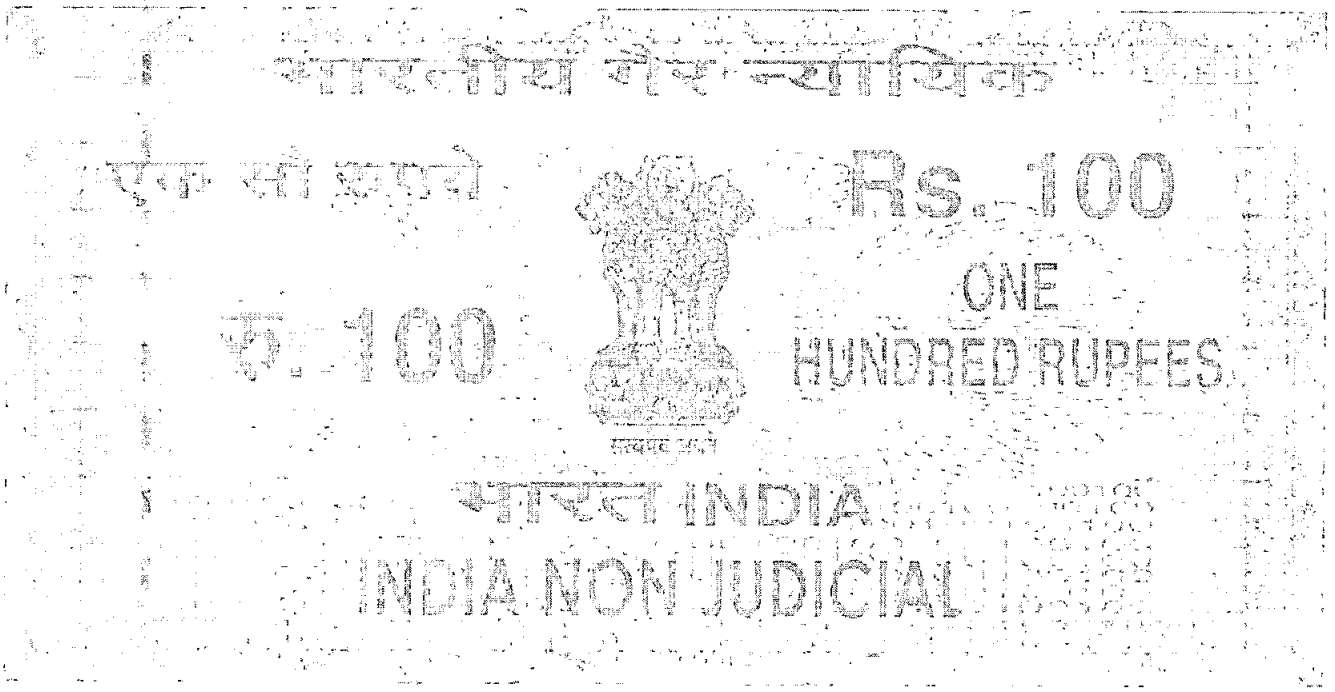
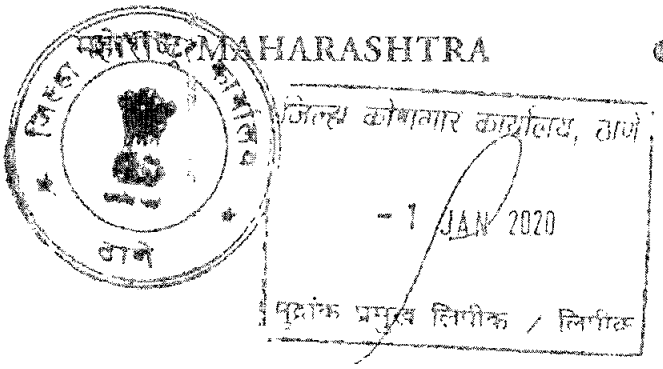


MAHARASHTRA © 2019 © VW 951258



CLINICAL TRIAL AGREEMENT

This clinical study agreement ("**Agreement**") is executed as of this the **30th day of December 2019**
("**Effective Date**") by and between:

Mediclin Clinical Research a firm, a Contract Research Organization, having its office at **Fourth Floor, Ambika Industries, Penkar Pada, Opposite Thakur Mall, Mira Road (E), Thane- 401 104, India** through its authorized signatory which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the "**CRO**").

AND

Doclin Clinical Research Services located at **445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka -590008, India** which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "**SMO**")

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3 JAN 2020

MEDICLIN CLINICAL RESEARCH
4th floor, Ambika Industries,
Penkar Pada Road,
Western Express Highway,
Mira Road (East), Thane-401 107

D.B Patil

3 JAN 2020

479861

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AND

KLES Dr. P.B. Kore Hospital & Research Center located at **Neharu Nagar Belgaum-590010, Karnataka, India** which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "**Institution**").

AND

Dr. Smitha K. S. affiliated to the institution, (hereinafter referred to as the "**Investigator**")
(Each a "Party" and collectively, the "Parties")

WHEREAS:

A. The Institution is a health care organization engaged in the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare, and has the facilities and personnel necessary to conduct the clinical trial;

B. Investigator is interested to conduct clinical trial in the Institution under his / her guidance and supervision.

C. CRO is a clinical services offering firm. CRO will perform on behalf of **Ajanta Pharma Ltd.** (sponsor)

D. CRO desires Institution and Investigator to conduct a study entitled **"A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension."**

E. **NOW THEREFORE** in consideration of the promises and mutual covenants herein contained, Parties hereby agree as follows:

1. SCOPE

1.1 The Study is of mutual interest and benefit to CRO and Institution and will further the Institution's instructional and research objectives in a manner consistent with the terms and conditions of this Agreement.

1.2 The Institution shall exercise its best efforts to carry out the research ("Study") set forth in the Protocol entitled **"A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension."**

2. CONDUCT AND PERIOD OF THE STUDY

2.1 The Investigator and the Institution shall conduct the study in accordance with the Protocol. The CRO, Investigator and Institution shall perform it in accordance with all applicable laws, government regulations and guidelines including but not limited to the Drugs & Cosmetics Act 1940 and Rules 1945: Schedule-Y (as amended from time to time), The Indian Council of Medical Research (ICMR) guidelines, Good Clinical Practices (GCP) and the standards conforming to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

2.2 The Study will be initiated in the institute only after EC associated with the institute approves the study.

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2.3 The Institution agrees that the CRO or its designee as clinical monitor may conduct routine monitoring visit at mutually convenient times and upon reasonable advance notice to the Institution. The clinical monitor will have direct access to all records and documents pertaining to the Study to ensure that it is conducted in accordance with the Protocol and applicable regulatory requirements and in terms of this Agreement.

2.4 The Study does not involve any Biological Samples to be tested as part of it.

2.5 The Clinical Trial will be effective on the 30th day of December 2019 and continue until the study is completed at Investigational Sites. The parties agree that no patient enrolment will occur until there is IRB/IEC approval of the Protocol by all the involving investigational site.

3. OBLIGATIONS, REPRESENTATIONS & WARRANTIES OF THE PARTIES

3.1 The Institution shall ensure proper conduct of Study.

3.2 The Investigators appointed by the Institution shall be responsible for obtaining signed informed consent form from each Subject prior to the Subject's participation in the Study from the designee.

3.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a study subject to participate or to continue to participate in this Study.

3.4 The investigator shall take reasonable efforts to recruit the agreed number of Subjects on a timely basis and the Parties shall take reasonable efforts to conduct the Study in accordance with the agreed time period.

3.5 The Institution and Investigator shall not permit the use of the material (instruments provided to capture voice) for any purpose (whether directly or indirectly) other than the conduct of the Study.

3.6 To the extent permitted by law, the Institution shall immediately inform CRO of:

3.6.1 Any intended or actual inspection, written inquiry or visit to the trial Site by any regulatory authority; or

3.6.2 Any queries by State or Central Information Commission under Right to Information Act (amended up to date) in connection with the Study and forward promptly to the CRO copies of any correspondence from any such authority.

3.7 The Institution and the Investigator shall keep complete and accurate records of the conduct of the Study and of all data in accordance with generally accepted industry standards and practices and applicable Law. The Institution will retain the documents in a safe and secure lock-and-key facility until the study ends. After the study is over, Institution will hand-over those to the CRO.

4. FINANCIAL ARRANGEMENTS

4.1 Cost and payment terms are set forth in **Appendix-B** attached to this Agreement and incorporated by reference.

4.2 The Mediclin Clinical Research shall reimburse the Investigational Site for all direct and indirect costs incurred in connection with the Clinical Trial up to **INR.19,125/ Subject** ("Cost"). The Mediclin Clinical Research shall pay EC fees as per actual cost which is in the amount of **INR. 88500/-** and which is payable upon signing of this agreement. Mediclin Clinical Research will pay the EC fees directly to the site Ethics Committee.

4.3 The parties agree that the Cost is based upon the reasonable costs for similar studies at like institutions and Investigational Sites have not been induced to participate in

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this Clinical Trial based on inducements from Mediclin Clinical Research. The parties estimate that the Cost is sufficient to support the Clinical Trial, but if certain patient care costs are expected to be covered by insurance or another third party payers and such patient care costs are denied, Sponsor on behalf of Mediclin Clinical Research agrees to reimburse the Investigator for the patient care costs not covered by insurance or third party payer which are necessary to conduct the Clinical Trial.

4.4 The Mediclin Clinical Research will not be liable for any payment in excess of the Cost except upon Investigator's written agreement.

4.5 Mediclin Clinical Research in turn will make the payment in accordance with the Payment Schedule to the Investigator as attached in **Appendix-B** incorporated herein.

4.6 Mediclin Clinical Research will pay amount to investigator by Cheque/ NEFT/ RTGS, as per terms and conditions applied.

5. TERM AND TERMINATION

5.1 Unless otherwise terminated earlier, this Agreement shall commence upon Effective date and will continue for a period of 5 years from the Effective Date or upon completion of the Study, whichever is earlier. 'Effective Date' means the date when this Agreement becomes effective which shall be the date of last signature hereto by the Parties.

5.2 Any Party may terminate this Agreement with immediate effect, at any time, if another Party is in breach of any of the defaulting Party's obligations hereunder (including a material failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of remedy, within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy. It is explicitly agreed and acknowledged by the Investigator and Institution that in case of termination of study, no further payment shall be made by CRO to the Institution or any other person under this agreement.

5.3 CRO may terminate this Agreement upon thirty (30) days prior written notice to the Institution or such shorter notice period as required by a Regulatory Authority, for any reason whatsoever.

5.4 Without limiting the generality of the foregoing, CRO may terminate this Agreement:

- 5.4.1 if the Institution is not performing the Study as required in the protocol;
- 5.4.2 in case of failure of the Institution to provide access to CRO representatives /Clinical monitor /Auditors all original medical records necessary to verify entries on study case report forms;
- 5.4.3 in case of an unauthorized replacement of Investigator;
- 5.4.4 if CRO determines that business or scientific considerations require termination of this Agreement (either full or in part);
- 5.4.5 if any malpractices adopted either by the Investigator or Institution or both.

5.5 Within Thirty days after the termination of this Agreement, the Investigator shall deliver to CRO completed CRF pages.

6. INDEMNIFICATION

6.1 To the maximum extent permitted by applicable laws, the Institution agrees to defend, indemnify and hold harmless the CRO and its respective directors, officers, employees and agents (the "Indemnities") and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a

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third party against an Indemnity for harm:

6.1.1 Arising out of or relating to the negligence or wilful misconduct or malpractices of the Institution, its employees and agents in performing their obligations under this Agreement;

6.1.2 Arising out of errors or omissions by Institution;

6.1.3 Arising out of or relating to the failure of the Institution, its employees and agents to comply with the provisions of this Agreement, the Protocol, or any written instructions of CRO concerning the Clinical Study; or

6.1.4 Arising out of the violation of applicable Law related to the conduct of the Clinical Study by the Institution, its employees or agents.

6.2 To the maximum extent permitted by applicable laws, CRO agrees to indemnify and hereby indemnifies, defend and hold the Site, its Principal Investigator, Sub-Investigators and study team, directors, officers and the support staff, agents, the trustees of the Institution harmless from and against any proven liability, loss, damage, costs, expenses, claims, demands and suits (including reasonable attorney's fees and expenses) including arising from and resulting out of (i) the breach of any of CRO representations, warranties or covenants set forth in this Agreement or (ii) the performance of the Study or any of its results / outcome including, adverse drug experiences or an injury, death to/of a Study subject directly or indirectly caused by or attributed to the Study , (iii) any injury or claim arising due to any defect / malfunction of the device used during the Study in accordance with the provisions of the Protocol and this Agreement.

6.3 Each Party shall use reasonable efforts to inform the other Party promptly of any circumstances of which it is aware that are reasonably likely to give rise to a claim or proceeding and shall keep the other Party reasonably informed of developments in relation to any claim of proceeding, even where a Party decides not to make a claim for indemnification under this Section 6. The Parties further agree that they have a right to retain their own counsel to conduct a full defence of any such claim or proceeding.

6.4 The Institution and CRO shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding concerning the Clinical Study.

6.5 No settlement or compromise of a claim or proceeding subject to indemnification under this Section 6 shall be binding on a Party without the prior written consent of the other affected Party (ies). A Party shall not unreasonably withhold such consent of a settlement or compromise. Without limiting the generality of the preceding, no Party shall admit fault on behalf of an indemnity or enter into a non-monetary settlement that places future obligations on an indemnity without the written approval of the indemnity.

7. CONFIDENTIALITY

"Confidential Information" means all information (including, without limitation, subject identity, Study Protocol(s), informed consent form, subject cards, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of CRO or CRO's Affiliates that are: (1) provided to the Institution in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

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7.1 Confidential Information and all tangible expressions, in any media, of CRO are the sole property of CRO. Each party shall endeavour to identify tangible Confidential Information provided to the other party as "Confidential" given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Institution agrees to treat CRO's Confidential Information as it would be its own proprietary and confidential information. Institution will only accept information from CRO which is required for conduct of the Study and which must be maintained for Institution's records.

7.2 Institution will make sure that it and Investigator agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose CRO's Confidential Information to any third party. Institution agrees not to disclose CRO's Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. The parties understand and agree that information communicated to EC is "Confidential and Privileged".

7.3 The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations in this Section 7 shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

8. INTELLECTUAL PROPERTY RIGHTS

8.1 All Intellectual Property Rights owned by or licensed to CRO prior to and after the date of this Agreement are and shall remain the exclusive property of CRO.

8.2 All Intellectual Property Rights owned by or licensed to the Institution prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical study, are and shall remain the exclusive property of the Institution.

8.3 All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Studies, the Investigational drugs, mobile application or the Protocols (the "Clinical Trial Intellectual Property") shall be the exclusive property of CRO/Sponsor and for this purpose, the Institution hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to CRO (or its nominate designee), all their rights and title in and to the Study tool throughout the world on perpetual basis. The Institution shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at CRO's expense, do all such other acts as CRO may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in CRO or its nominate designee.

8.4 The Institution shall promptly disclose to CRO any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information.

9. MISCELLANEOUS

9.1 All notices required to be given by one Party to the other shall be deemed to have

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been properly served when sent by a registered post or any other means of communication acceptable in law to the addresses mentioned in the first page of this Agreement or such appropriate addresses available in public domain.

9.2 No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement.

9.3 Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent contractor. Nothing under this Agreement shall create any other relationship between the Parties including without limitation one of principal and agent, employer and employee, or partnership.

9.4 The Institution will be responsible for payment to its employee study team members and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the Investigators, study team members or employees or agents may be entitled to receive for performing services. Institution will be solely responsible for withholding and paying all applicable taxes of whatsoever in nature, statutory contributions, benefits, dues etc. that may be payable to its employees and/or agents.

9.5 This Agreement constitutes the entire Agreement between the Parties and supersedes all prior oral and written understandings between the Parties on the subject matter of this Agreement. Any Exhibit, Annexure or otherwise any documents, including but not limited amendment or modification made in reference with this Agreement shall be valid if the same is incorporated in writing on the terms that may be mutually agreed and signed by the authorized signatories of the respective parties.

9.6 The Parties hereby agree that any provision/s of this Agreement which is held to be invalid and unenforceable in law shall not by itself make this Agreement invalid nor effect the other provisions of this Agreement and the other terms shall remain fully enforceable and valid in law.

9.7 Institution will not assign this Agreement without the prior written consent of CRO. CRO may assign any or all of its rights and obligations under this Agreement at any time, provided that CRO ensures the assignee is bound by the terms hereof.

9.8 Institution shall not subcontract the whole or any part of the performance of the clinical Studies without the prior written consent of CRO. This Agreement ensures to the benefit of and binds the Parties and their respective administrators, successors and permitted assigns, and with respect to the Investigator, heirs and executors.

9.9 This Agreement and the obligations of the Parties shall be governed by and construed in accordance with the laws of India. The Parties agree to submit to the exclusive jurisdiction of courts at Pune in connection with this Agreement.

9.10 Neither Party to this Agreement shall be liable for breach of this Agreement to the extent caused by or arising from prohibition or restriction by law or regulation of any Government, fire, flood, storms, weather, strike, lock-out or other labour problems, accident, riots, acts of God, breakdown of communication facilities, breakdown of web host, breakdown of internet service provider or other events beyond that Party in breach. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. In the event of a delay lasting for four (4) weeks or more, the non-affected Parties shall have the right to terminate this Agreement in accordance the term of this Agreement.

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9.11 The provisions of this Agreement which, by their terms, require performance after the termination or expiration of this Agreement, or have application to events that may occur after the termination or expiration of this Agreement, will survive the termination or expiration of this Agreement. All indemnity obligations and any applicable indemnification procedures will be deemed to survive the termination or expiration of this Agreement.

10. INTERPRETATION

10.1 Unless the context requires otherwise:

10.1.1 References to this Agreement are to this Agreement as it is from time to time amended;

10.1.2 Headings are for convenience only and shall not affect interpretation;

10.1.3 References to the singular include the plural and vice versa, and references to one gender include all genders;

10.1.4 Any phrase introduced by the expressions "including", "include" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

10.1.5 Reference to any law: shall be deemed to include any bye-laws, licences, statutory instruments, rules, regulations, orders, notices, directions, consents or permissions made under that law; and shall be construed as referring to any law which replaces, re-enacts, amends or consolidates such law (with or without modification) at any time;

10.1.6 References to "writing" or "written" include any modes of reproducing words in a legible and non-transitory form but do not include writing on the screen of a visual display unit or other similar device;

10.1.7 References to a numbered clause are references to the clause of or to this Agreement so numbered.

10.2 The parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favouring or disfavouring any party by virtue of the authorship of any provision of this Agreement.

IN WITNESS WHEREOF the parties have executed this Agreement after carefully reading the contents of this Agreement out of their free will and consent without any kind of force or coercion on them.

BY CRO **Name:** Dr. Ravindra Mote **Designation:** Director **Signature with Stamp:** **Date:**	30 DEC 2019
BY SMO **Name:** Mr. Maruti Patil **Designation:** Managing Director **Signature with Stamp:** **Date:** 21 JAN 2020	

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BY INVESTIGATOR **Name:** Dr. Smitha K. S. **Designation:** Principal Investigator **Signature with Stamp:** **Date:** 21 JAN 2020
BY INSTITUTION **Name of Hospital:** KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India **Name:** M.V. Jali **Designation:** MD and CEO **Signature with Stamp:** **Date:** 05 Feb 2020

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APPENDIX- A

Study Name	A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension.
Protocol ID	APL/CT/18/03
Site Name	KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India
Name of Investigator	Dr. Smitha K. S.

Instruction for Payment Payee Details	
Payee Name	Doclin Clinical Research Services
PAN No	AZXPP8818R
GST No	29AZXPP8818R1ZP
Bank Account Number	919020049795418
Bank Name	Axis Bank
Bank Swift Code / IFSC Code	CHASUS33/UTIB0001690
Bank Branch Address	Nehru Nagar, Ratna Plaza, Cts. No. 10593 A& B, Kolhapur Circle, Belgaum 590010

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APPENDIX-B

Given below is the suggested financial break-up of total trial grant allocated to each center. You are requested to go through the same & revert as soon as possible regarding approval of this budget, following which the final financial agreement will be sent for your signature.

Payment Head	Amount (INR)
Total amount	INR. 19125/Subject.

Protocol ID: APL/CT/18/03		
Site Name	KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India	
Investigator Name	Dr. Smitha K. S.	
Target of enrolment of subject		**25**
Note: This is a competitive recruitment trial having 210 subjects.		
Visit Description (Per Patient/ Visit)		
Visit Details	**Day wise Visit**	**Cost (INR)**
Screening (V1)	Day -3	2,000/-
Baseline/ Randomization (V2)	Day 0	1,500/-
Visit 3 (V3)	Day 14 ± 2 days	2,000/-
Visit 4 (V4)	Day 28 ± 2 days	1,500/-
Visit 5 (V5)	Day 56 ± 2 days	2,000/-
Visit 6 (V6)	Day 84 ± 2 days	2,000/-
Screening to End of Treatment Total		**11000/-**
Laboratory Investigations and ECG (at Visit-1 and Visit-6) Inclusive of all		3,500/-
IOH @ 25%		3,625/-
Subject travel reimbursement		1000/-
Grand Total		**19125/-**
Note: 1. Maximum cost per subject should not be more than INR.19125/-.		

EC fees as per actual.
After monitoring visit, Monitor will assure the subject data as per regulatory requirements and will release the payments within 15 working days.

Medicin Clinical Research MUMBAI

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INVESTIGATOR CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (the "**Agreement**") effective as of the later of the dates appearing on the signature page, is entered into by and among, *Dr. Jyothi Hattitholi, Consultant Chest Physician* (**"Principal Investigator"**) at KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010 Karnatka India (**"INSTITUTION"**), SIRO Clinpharm Pvt Ltd. a company incorporated under the laws of India whose principal place of business is located at Kalpataru Prime 1st Floor, Unit nos 3 and 4, Plot no D-3 Road no 16 Wagle Industrial Estate, Thane (West) – 400604 Maharashtra., INDIA (hereinafter referred to as "SIRO")

Authorised Signatory
For Thane Bharat Sahakari Bank Ltd.
H.O. Branch Thane

WHEREAS the Principal Investigator is engaged in the treatment of subjects with potential exposure the COPD; and is associated with the Institution in her capacity as *Consultant Chest*

WHEREAS the INSTITUTION is a Private Multispecialty Hospital

WHEREAS, the SMO is engaged in management of the trial at the Institute ad assisting the Principal Investigator, and,

WHEREAS SPONSOR is engaged in the research and development of human pharmaceutical products

WHEREAS,SPONSOR is the Sponsor of the clinical study CLR_18_09 Titled **Pharmacodynamic Bioequivalence of two formulations of Ipratropium Bromide (21 mcg) HFA in Subjects with Chronic Obstructive Pulmonary Disease: A Randomized, Observer Blind, Three Treatment, Three Period, Six Sequence, Single Dose, Crossover, Placebo and Active Controlled Comparative Study** (the "Clinical Study")

WHEREAS SIRO is the Clinical Research Organization acting on behalf of SPONSOR to administer the clinical study

WHEREAS the Principal Investigator is engaged in the treatment of subjects with potential exposure to Chronic Obstructive Pulmonary Disease and

WHEREAS, the Principal Investigator wishes to participate in the Clinical Study and SPONSOR wishes to have the participation of the Principal Investigator
NOW THEREFORE, the parties agree as follows

1. Protocol

1.1 Title The Clinical Research protocol CLR_18_09 titled a "Pharmacodynamic Bioequivalence of two formulations of Ipratropium Bromide (21 mcg) HFA in Subjects with Chronic Obstructive Pulmonary Disease: A Randomized, Observer Blind, Three Treatment, Three Period, Six Sequence, Single Dose, Crossover, Placebo and Active Controlled Comparative Study", which will govern the performance of the Clinical Study, has been prepared by SPONSOR and accepted by the Principal Investigator (the protocol, together with any of its subsequent amendments, shall be referred to in this Agreement as the "Protocol")

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1.2. Conflicts. In the event of a conflict between the terms and conditions set forth in this Agreement and the Protocol, this Agreement will govern.

1.3. GCP. If generally accepted standards of Good Clinical Practice ("GCP") relating to the safety of subjects participating in the Clinical Study require a deviation from the Protocol, these standards will be followed. Any party who becomes aware of the need for a deviation from the Protocol will immediately inform the other parties to this Agreement of the facts causing the deviation as soon as the facts are known to the party. In addition, the Principal Investigator will promptly inform the Institution's institutional review board ("IRB") of the deviation.

1.4. Amendments. SIRO, on behalf of SPONSOR, may also, 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

2. Principal Investigator and SMO

2.1. 2.1 The Principal Investigator and SMO shall carry out the Clinical Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement. The Principal Investigator and SMO will also be responsible for the direction of the Clinical Study in accordance with any applicable Institution policies. The Principal Investigator and SMO shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement. The Principal Investigator, SMO or the INSTITUTION should inform SIRO and SPONSOR in the event of a discrepancy between the terms of the Protocol, this Agreement and its own INSTITUTION policies within twenty-one (21) working days of the Effective Date of this Agreement. In the absence of any such intimation by the Principal Investigator, SMO or the INSTITUTION, the terms of the Protocol and this Agreement shall prevail The Principal Investigator and SMO shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement

3. Study Initiation and Subjects

3.1. It is anticipated that the Clinical Study will commence upon execution of this Agreement, that subject enrollment will be completed on or about June 2020,and that the Clinical Study will be completed on or about December 2020, unless otherwise terminated in accordance with the provisions of Para 17 of this Agreement.

3.2 If however, the Clinical Study obligations have not been completed by Dec 2020, the Principal Investigator and / or SMO shall continue with, and complete all obligations under this Agreement All payments shall correspond with the appropriate milestone, as listed in Schedule A

3.3. The Clinical Study will involve the enrollment of a maximum of 07subjects (provided there may be an increase in enrollment upon SIRO request) meeting all Protocol eligibility requirements ("Subjects"). SIRO shall not be obligated to pay any sums for tests performed on subjects who do

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not meet all Protocol eligibility criteria or for additional subjects who are enrolled in the Clinical Study without SIRO's prior written approval

4. Patient Information and Consent

4.1 It is the Principal Investigator's responsibility to explain the Study to each potential patient (parent and/or legal guardian of the infant) and obtain written informed consent before any Study procedures are performed. This is an unconditional prerequisite for participation of a patient in the Study. The Investigator shall inform the subject or his/her nominee(s) for their rights to contact the sponsor or SIRO (whosoever has obtained permission from the licensing authority for the conduct of clinical trial) for the purpose of lodging claims in case of any trial related injury/death. The explanation shall at least include all points listed in the International Councilon Harmonisation ("ICH") Guideline for Good Clinical Practice, section 4.8.10 including but not limited to applicable regulations, and it must be given both verbally and in writing in compliance with ICH-GCP, ethical principles based on the Declaration of Helsinki in its current version and national requirements. Patients shall be given sufficient time to consider their participation in the Study. Consent must be documented by the patient's dated signature on the trial informed consent form. A copy of the signed and dated information and consent form must be provided to the patient. In the event the Patient is not able to give informed consent, the same may be obtained from a legally acceptable representative. For the purpose of this section, a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the Patient as provided by the applicable law(s) of India. In the event the Patient and where required his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the trial informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the trial informed consent form.

4.2. Provision of consent will be confirmed in the CRF as well as by the Principal Investigator's signature on the consent form. The signed and dated declaration of informed consent will remain at the INSTITUTION and must be safely archived by the Principal Investigator, so that the forms can be retrieved at any time for monitoring, auditing and inspection purposes.

5. Representations And Warranties

5.1. **No Inconsistent Obligations or Constraints.** Institution and Principal Investigator each represents and warrants that it is qualified and permitted to enter into this Agreement and that the terms of this Agreement are not inconsistent with its other contractual arrangements. Institution and Principal Investigator each warrants that it is not constrained by any existing agreement in performing its obligations under this Agreement.

5.2 **Legal and Binding Agreement.** Institution and Principal Investigator each represents and warrants that this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms.

5.3 **No Impairment; No Conflict.** During the term of this Agreement, Institution and Principal Investigator each warrants that it shall not enter into any agreement to provide services which would in any way (a) materially impair his, her or its ability to complete participation in the Study or (b) constitute a conflict of interest with Sponsor's development of Study Product.

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5.4. **No Pending Litigation; No Action by FDA.** Institution and Principal Investigator each represents and warrants that (a) it is not currently involved in any litigation, and is unaware of any pending litigation proceedings, relating to Institution's and/or Principal Investigator's role in the conduct of a clinical trial for any third party; and (b) it has not received any warnings from the FDA or other Regulatory Authority relating to services it has provided to third parties during the conduct of a clinical trial

6. Insurance Coverage

6.1 SPONSOR shall adequately insure each and every Participating patient covering any injury or illness suffered as a direct result of their participation in this Clinical Study. Provided that the SPONSOR shall not be responsible to provide for insurance coverage with respect to any injury (including death) or illness arising as a result of (i) negligent acts of Principal Investigator, and/or INSTITUTION and/ or SMO with respect to activities or services undertaken pursuant to this Agreement; (ii)improper or negligent administration or use of the Clinical Study Drug during the course of the Clinical Study by the Principal Investigator.; or (iii) in violation of any and all applicable Central, State or Local laws rules and regulations in India by Principal Investigator, INSTITUTION, SMO and SIRO. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage

6.2 INSTITUTION, SMO and the Principal Investigator, shall have adequate insurance coverage for any claims arising from their negligence, willful misconduct and other actions or omissions. The Institution and the Investigator will provide a copy of their insurance certificate to SIRO and the SPONSOR upon signature of this Agreement.

7. Ethics Committee Approval

7.1 The Study will only be started when full written approval of/ favorable opinion on the Protocol has been obtained from the concerned local or regional Ethics Committees (EC) / Investigational Review Board (IRB). It is the Principal Investigator's responsibility to obtain EC/IRB approval/opinion for the Protocol and all subsequent amendments, in compliance with the national regulatory requirements and laws

8. Study Management

8.1 Case Report Form Handling. The Principal Investigator and/ or SMO shall be responsible for providing correct Case Report Forms ("CRF") according to the following.

8.1.1 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

8.1.2 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 SIRO/SPONSOR for data management and biometric analysis

8.1.3 The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator and/ or SMO shall

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ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to SIRO/SPONSOR

8 1.4 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

8 1 5 If CRFs are not complete the Principal Investigator and/ or SMO shall be obliged to complete them on request of SIRO/SPONSOR

8 2 Source Data The Principal Investigator and/ or SMO 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 they comprise:

- Signed informed consent form
- Patient hospital file and individual clinical notes.
- Laboratory reports
- Pharmacy records
- Study specific source documents (e.g x rays, ECG tracings)
- Appropriate sections of the CRF where data are recorded directly onto specific forms
- Other reports and records of any procedure performed in accordance with the Protocol.

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 15 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 SIRO/SPONSOR

8.3 **Investigator Study File and Archiving.** The INVESTIGATOR and/ or SMO 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:

- Signed protocol and amendments
- Investigator s Brochure and updates
- EC composition approval(s)/opinion correspondence/reporting
- Notifications of regulatory authorities
- CVs and signature sheet for key study personnel (e.g. investigators study nurses)
- Signed study agreements including financial agreement
- Trial initiation report
- Approved and signed informed consent forms
- Patient insurance certificate
- CRF s (investigator s copy)
- Data correction forms (copies)
- S/ E documentation and related correspondence/reporting
- Shipping/accountability/destruction records for investigational product and material
- Certificate of analysis
- Instructions for handling of investigational product and materia

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- Laboratory accreditation/certification and up-to-date reference ranges of normal values.
- Screening, enrollment, and monitoring logs and subject identification code list
- Appointment diaries
- Study related correspondence with SPONSOR or SIRO

8.4 **Documentation and Material (Supplies).** All supplies provided to the Principal Investigator and/ or SMO 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.

The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of Investigational Product and any other material for the Study, supplied by SIRO/SPONSOR (except documentation required to be retained by the Principal Investigator) must be returned to SIRO/SPONSOR or destroyed at site, alternatively. In the latter case the identification and quantity of each unit of study medication, the method of destruction, and the person in charge must be documented.

8.5. **Monitoring, Quality Assurance, and Inspection by Authorities.** The Study will be monitored by SIRO. 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.

SIRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring visits throughout the Study. The tasks of the monitor comprise the following:

- to ensure protocol adherence
- to verify the data in the CRFs against source documents (SDV),
- to check progress of the study and to motivate, if necessary,
- to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
- to check all data for possible SAEs and AEs,
- to review signed informed consent forms for signatures and date of consent,
- to ensure accurate record of drug accountability,
- to ensure adequate storage of study supplies,
- to collect completed CRFs
- to discuss and help resolve any problems,
- to verify adequate insurance coverage undertaken by PI,
- to verify the ICF(s) as per the applicable regulatory guidelines.

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.

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 will be allowed for monitoring visits. Follow-up correspondence between the site and SIRO relating to apparent inconsistencies or clarification of CRF entries shall be kept on file at both SIRO and the site.

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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 SIRO.

This Study shall be audited on behalf of SPONSOR to assure GCP compliance as well as validity of the study data according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of a contract organization selected by SPONSOR.

For monitoring visits and in case of audits and inspections by authorities the Principal Investigator and/ or SMO must provide direct access to the complete study records including CRFs, original source data, study documentation, and, if necessary, any additionally required background data. Furthermore, access to Study related facilities must be ensured.

8.6 **Confidentiality of Patient Records.** The INSTITUTION, SMO and the Principal Investigator must assure that study patients' anonymity will be maintained, and that their identities are 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 and SMO is obliged to maintain a subject identification code list showing the patients' full names and dates of birth together with the corresponding patient identification numbers to allow revealing identity of any subject.

The Principal Investigator and SMO agrees that representatives of SPONSOR, SIRO, of the responsible EC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and SIRO guarantee for their representatives that patient data will be treated confidentially. Monitors and auditors are bound to secrecy.

8.7 Principal Investigator and SMO agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose SIRO and Sponsor Confidential Information to any third party. Institution and Principal Investigator agrees not to disclose SIRO and Sponsor Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution and Principal Investigator shall safeguard SIRO and Sponsor Confidential Information with the same standard of care that is used with own Confidential Information, but in no event less than reasonable care. The parties understand and agree that information communicated to EC is 'Confidential and Privileged.

8.8 The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and, where Confidential Information is also Personal Information, the obligations under this Section shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

9. Budget

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Cost and payment terms with all the Payee details(along with the GSTIN of all the Parties) are set forth in Schedule "A" attached to this Agreement and incorporated by reference All the payment obligations of the Sponsor shall be routed through SIRO

All payments payable by SIRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site GST will be paid, if applicable, on generation of valid invoice showing the amount of GST to be charged before any payment is made under this Agreement

All invoices should have GSTIN (Goods and Service Tax Identification Number) along with HSN code for services as mandated by GST provisions. This is mandatory to ensure compliance with GST.

In case the site defaults in making timely GST payments then SIRO shall retain 18% of each payment of the contract price payable to the Institution for a period of 45 days from the release of payment However, such retention shall not be applicable in case the Institution discharges the applicable GST and files the GST Returns in relation to such payments, and the same is being reflected in SIRO's Returns.

In case of any non-compliance of any provisions under the GST Legislations by Institution, such Institution alone shall be liable to compensate SIRO for any losses arising to SIRO due to such non-compliances as well as shall also be liable to pay interest and/or penalty imposed by the Statutory Authorities and/or other legal fee or expenses incurred by the SIRO in this regard

10. Data and Information

10.1 **Confidential Information.** During the term of this Agreement and for a period of ten (10) years after termination of this Agreement, the Principal Investigator and SMO shall not disclose or use for any purpose other than performance of the Clinical Study information including but not limited to any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data, both technical and non-technical disclosed to the Principal Investigator by SIRO or SPONSOR ("Information") The obligation of non-disclosure shall not apply to the following:

10.1.1 Information at or after such time that it is or becomes publicly available through no fault of the Principal Investigator; and/ or SMO;

10.1.2 Information that is already independently known to the Principal Investigator and/ or SMO as evidenced by their prior written records;

10.1.3 Information at or after such time that it is disclosed to the Principal Investigator and/ or SMO on a non-confidential basis by a third party with the legal right to do so;

10.1.4 Information developed by the Principal Investigator and/ or SMO without the use of SIRO's or SPONSOR's Information as evidenced by their written records or

10.1.5 Information required to be disclosed by law

10.2 **Medical Records** In the event that either SIRO or SPONSOR come into contact with Subjects' medical records, such party shall hold in confidence the identity of the Subject and shall comply with the Information Technology (Reasonable security practices and procedures and

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sensitive personal data or information) Rules, 2011 made under the Information Technology Act, 2000 (and all other applicable law(s) with respect to the confidentiality of such records

10.3 **Trading in Securities** Securities and Exchange Board of India (SEBI) interalia, prohibits any person either on his own behalf or on behalf of any other person, deal in securities of a company listed on any stock exchange when in possession of or is likely to have access to or has received any unpublished price sensitive information. The Principal Investigator, by virtue of their participation in the Clinical Study, has access to data and information arising out of the conduct of the Clinical Study, which is material non-public information that belongs to SPONSOR. The Principal Investigator and SMO agrees not to use, or cause any other person to use, the data and information arising out of the Clinical Study to purchase or sell securities in SPONSOR Company.

10.4 **Proprietary Rights.** All information resulting from the Clinical Study conducted under this Agreement, including all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not ("Data") shall be fully disclosed by the Principal Investigator and SMO to SPONSOR. All Data shall be the sole property of SPONSOR and SPONSOR shall have the unrestricted right to freely utilize all such Data in whatever manner it desires.

Principal Investigator, SMO and/or the INSTITUTION agree to undertake such actions reasonably requested by SPONSOR to give effect to such ownership and agrees to sign, execute, affirm all documents including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

10.5 **Resignation etc.** of the Principal Investigator: The INSTITUTION shall inform SIRO in case the Principal Investigator ceases to be associated with the INSTITUTION for any reason during the course of the Study. They shall also replace the Principal Investigator in case SIRO so desires and render all assistance to safeguard patient safety and Study data.

11. Drug Safety

11.1 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 SPONSOR/SIRO's medical monitor concerning any AEs.

11.2 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.

11.3 The Principal Investigator must immediately report all serious adverse events (as defined in the protocol)(within 24 hrs of occurrence of SAE), which occur during the course of the Study and up to the date of the patient's last visit, to the following addressee given below. The SAE Report form, will be used for documentation and reporting.

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Licensing authority. All SAE forms are to be e-mailed or faxed at Email ID: dci@nb.nic.in and Fax no :011-23236973

Sponsor: All Initial and follow up SAE reports are to be sent on the following email ID: CT.SAE@sunpharma com and Mahesh.kumbhar@sunpharma com and clinical.safety@sparcmail.com /of the Sponsor

Ethics Committee: All Initial and follow up SAE reports are to be sent viae- mail – kleclinicalresearch@gmail.com

A Due Analysis report has to be submitted to the following addressee within 14 calendar days of occurrence to the DCGI (Licensing Authority), Ethics Committee Chairman and Head of the Institution for all the Initial and Follow-up information until stabilization/ resolution of the event.

- **Licensing authority:** For all SAEs as hard copy via courier at DCGI address

The Drugs Controller General (India)
CDSCO Extn Office , *3rd Floor, CGHS Dispensary Sector-3* *Sadiq Nagar New-Delhi-110049* *Fax: 011-23236973*

- Chairman of Ethics Committee: For all SAEs as hard copy via courier at
  Dr Subarna Roy- Chairman
  Institutional Ethics Committee, KAHER
  JNMC Campus Nehrunagar Belagavi-590010 Karnataka India
  Email: kleclinicalresearch@gmail.com
- Head of the Institution: For all SAEs as hard copy via courier
  Dr M.V Jali – MD & CEO
  KLES Dr Prabhakar Kore Hospital & Medical Research Centre
  Nehrunagar Belagavi-590010 Karnataka India
  medicaldirector@klehospital.org

11.4. 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 SIRO shall be informed by telephone and followed immediately by fax but not later than within 24 hours of occurrence of SAE

11.5. SIRO undertakes to notify the Principal Investigator of all Suspected Unexpected Serious Adverse Reactions (SUSARs), which occur during the course of the Study in any other location and Periodic SAE listings, which are reported by SPONSOR to health authorities, at an interval of every 3 months The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, SUSARs, Periodic SAE listings and of findings that could adversely affect the patients' safety could have an impact on the conduct of the study, or could alter the ECs / IRBs approval to continue the study.

11.6. SIRO will be responsible to notify on time the health authorities in India

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12. Study Drug and Study Materials

12.1 **Study Drug.** SIRO, on behalf of SPONSOR will provide Clinical Study Drug for the Clinical Study. The use of the Clinical Study Drug for any purpose outside of the Clinical Study is prohibited by this Agreement. While SIRO in no way condones the use of the Clinical Study Drug for any purpose outside of the Clinical Study, if such work is performed, all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Data in accordance with this Agreement.

12.2. **Materials.** Access to Study Materials shall be limited to only those persons who under the Principal Investigator's direct control will be using Study Materials for the Clinical Study. The term "Study Materials" shall include the Clinical Study Drug, reagents and materials derived from Subjects enrolled in the Clinical Study, including, but not limited to, blood, bone marrow, sera, and other biological materials.At no time shall any Study Materials be used for any purpose other than as described in the Protocol or transferred to any third party without SPONSOR's prior written consent. Upon termination or completion of the Clinical Study, all unused Study Materials shall be returned to SPONSOR or at SPONSOR's sole option, destroyed.

13. Publications

13.1. The Principal Investigator shall not publish any article or paper nor make any presentations nor assist any other person in publishing any articles or papers or in making any presentations relating or referring to

(a) the Study or any results, data or insights therefrom,

(b) the Services performed hereunder, or

(c) any data, information or materials obtained or generated in the performance of its obligations hereunder, in whole or in part, without the prior written consent of SIRO and SPONSOR, which consent may be granted or withheld depending on the Study Sponsor's sole discretion.

13.2. Any publication or disclosure by the Principal Investigator, SMO and/or Institution contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7), (12) & (13), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

14. Use of Name and Advertising

14.1 **Use of Name.** The INSTITUTION / Principal Investigator / SMO and SIRO, on behalf of SPONSOR, shall each obtain prior written consent from the other before using the name, symbols or marks of the other, in any form or publicity in connection with the Clinical Study. If the INSTITUTION or SIRO is legally required to make any disclosure that identifies the existence or terms of this Agreement, then either may do so with prior written consent from the other.

14.2 **Advertising.** In the event that the Principal Investigator elects to advertise to recruit Subjects for enrollment in the Clinical Study, Principal Investigator will provide a copy of any such

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advertisement to SIRO / SPONSOR for prior approval In addition, Principal Investigator will obtain Institutional Review Board and Ethics Committee approval of all advertisement prior to use. Any promotional representation or suggestion that an investigational drug is safe or effective for the purposes for which it is under investigation is not permissible / a violation of the United States Code of Federal Regulation 21 CFR 312 7(a) (Strike out if not applicable depending upon the country of the sponsor).

14 3. Any use of name and advertising or disclosure by the Principal Investigator and/or Institution contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7), (12) & (13), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof

15. Intellectual Property Rights

15.1 All Intellectual Property Rights owned by or licensed to Sponsor prior to and after the date of this Agreement are and shall remain the exclusive property of Sponsor

15.2. All Intellectual Property Rights owned by or licensed to the Institution or the Principal Investigator prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of the Institution or the Principal Investigator as applicable

15.3. All Intellectual Property Rights owned by or licensed to SIRO prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of SIRO, as applicable

15.4. All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Study/trial the Investigational drug or the Protocol (the "Clinical Trial Intellectual Property") shall be the exclusive property of Sponsor and for this purpose, the Institution and the Principal Investigator hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to Sponsor (or its nominate designee), all their rights and title in and to the Clinical Trial Intellectual Property throughout the world on perpetual basis The Institution and the Principal Investigator shall execute and deliver, and shall cause the trial site team members to execute and deliver all such documents and, at Sponsor's expense do all such other acts as Sponsor may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in Sponsor or its nominate designee.

15 5 The Institution, SMO and the Principal Investigator shall promptly disclose to Sponsor any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information

16. Compliance with Law; Financial

16 1 The Principal Investigator and the INSTITUTION shall perform the Clinical Study in compliance with generally accepted standards of Good Clinical Practice as defined in U S Code of Federal Regulations 21 C F R the Protocol instructions provided by SIRO and all applicable

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local state and federal laws and regulations governing the performance of clinical investigations including but not limited to the International Conference on Harmonization ("ICH") Tripartite Guideline for Good Clinical Practice ("GCP"), the Indian Drugs and Cosmetics Act 1940, the New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Rules, 1945 and any Rules and amendments thereunder the CDSCO-GCP,. The Principal Investigator shall provide SIRO with sufficient accurate financial information to allow SIRO to submit complete and accurate certification or disclosure statements as required under U S Code of Federal Regulations, 21 C F R 54 The Principal Investigator shall also promptly update this information if any relevant changes occur during the course of the Clinical Study and for one year following the completion of the Clinical Study The Principal Investigator shall retain any records mutually agreed to by SIRO resulting from the Clinical Study for the time required by applicable local and federal regulations and to allow for inspection of all such records including the Subjects' medical records The informed consent form signed by the Subjects shall provide for access to the Subjects' medical records by SIRO and by agencies such as the FDA.

17. Debarment

17.1 The Principal Investigator certifies that neither the Principal Investigator nor any person employed by the Principal Investigator or any subcontractor to perform any services in connection with the Agreement has been subject to any legal or regulatory discipline, nor ever been suspended, debarred, or is under any medical license limitation or condition, or otherwise disqualified from providing medical services by any governmental, regulatory or administrative body or organization within their jurisdiction

18. Indemnification

18 1 To the maximum extent permitted by applicable laws, SPONSOR warrants that they shall defend, indemnify and hold harmless SIRO, PRINCIPAL INVESTIGATOR, INSTITUTION SMO and any of their agents and employees ("Indemnitees of Sponsor") from any and all liabilities claims actions or suits for personal injury or death directly arising out of the use of the Clinical Study Drug during the course of the Clinical Study in accordance with the Study Protocol

18 2 The indemnity granted in this Article 18 1 shall not apply in the event when such liability, damage, loss or expense was caused by the failure of an Indemnitee to

18 2 1 adhere materially to the terms of the Protocol;

18 2 2 comply with government regulations or requirements, or

18 2 3 conduct the Clinical Trial in accordance with generally accepted medical standards including avoidance of negligence and willful misconduct or

18 2 4 carryout its obligation without any error or omission

18 2 5 the reason of loss/ damage is not directly and solely attributable to the SPONSOR

18 3 SIRO warrants that it shall indemnify, defend and hold harmless SPONSOR, INSTITUTION, SMO and Principal Investigator, including their agents and employees (the "Indemnitees of SIRO") from

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any and all liabilities claims actions or suits for personal injury or death directly arising out of (i) negligent or deliberate wrongful acts of SIRO or its employees during the term of this Agreement, except to the extent that the same is caused as a result of the Project Materials provided by the Sponsor or adhering to the instructions of the Sponsor or Applicable Laws while rendering the Services or due to reasons attributable to the SPONSOR, INSTITUTION or Principal Investigator and their agents and employees, (ii) breach of confidentiality; (iii) non-compliance with the applicable laws, (iv)

18.4 The indemnity granted in Article 18 shall apply separately to each Indemnitee in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

18.5 Each party warrants that it shall provide a a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed The indemnifying Party shall have the right to settle claims at its sole expense.

18.6. The Principal Investigator/ INSTITUTION/ SMO shall promptly notify SIRO and SPONSOR of any claim for which indemnity may be sought The Principal Investigator /SMO/ INSTITUTION shall fully cooperate with SPONSOR / SIRO and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement. If the claim or action is asserted, the Principal Investigator shall have the right to select and obtain representation by separate legal counsel as long as the Principal Investigator pays for all costs and expenses incurred by it for the separate counsel

18.7 SPONSOR warrants that it maintains policies or programs of insurance or self insurance at levels sufficient or have SIRO to maintain such programs of insurance at the cost of SPONSOR to support the indemnification obligations assumed under this Agreement. Upon request, SPONSOR will provide evidence of their insurance or self-insurance

18.8. The Principal Investigator and INSTITUTION each shall indemnify, defend and hold harmless the Sponsor, including its agents and employees, and SIRO including its agents and employees, against any losses suffered and from all liabilities, claims, actions or suits for personal injury or death directly arising out of the negligence willful misconduct or any other act or omission by the Principal Investigator or the INSTITUTION, or by their agents and employees, during the course of the Clinical Study

18.9 The Principal Investigator and the INSTITUTION each shall also indemnify defend, and hold harmless the Sponsor and SIRO against

i any and all loss, costs claims actions liability and/or suits (including without limitation interest penalties and reasonable attorneys' fees) on the Sponsor or SIRO due to negligence, gross negligence or intentional misconduct of Principal Investigator and/or INSTITUTION in connection with its performance of the services obligations responsibilities and undertakings under this Agreement

ii Principal Investigator's and/or INSTITUTION's violation of any and all applicable Central State or Local laws rules and regulations of India

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iii Principal Investigator's and/or INSTITUTION's breach or default in performance of its obligations in connection with a Study.

iv Principal Investigator's and/or INSTITUTION's material deviation from the Protocol or other written recommendation or instructions furnished by SPONSOR through SIRO to Principal Investigator and the INSTITUTION for the Study.

v Principal Investigator's and/or INSTITUTION's failure to complete the Study and any such delay attributable solely to Principal Investigator's and/ or INSTITUTION's willful misconduct, negligence or mistakes and/or or failure to comply with its obligations under this Agreement

Without prejudice to any other Section, the reference to Principal Investigator and INSITUTION above includes reference to its agents and employees

19. Independent Contractor

19.1 The parties to this Agreement hereby agree that the Principal Investigator and Institution are independent contractors hereunder and are not employees or agents of the SPONSOR or SIRO. The Principal Investigator and INSTITUTION further agree that neither they nor their employees or agents shall make any claim against the SPONSOR or SIRO for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers' compensation, disability or unemployment benefits or employee benefits of any kind. Further their agents and employee shall not be considered to be employees of the Sponsor or SIRO under any circumstance

20. Termination

20.1 This Agreement may be terminated:

20.1.1 by the Principal Investigator upon thirty (30) days' prior written notice.

20.1.2 by SIRO on behalf of SPONSOR immediately upon thirty (30) days written notice.

20.1.3 by SIRO immediately if the Principal Investigator is unable to continue to serve and a successor acceptable to SIRO is not available or

20.1.4 upon the occurrence of an event qualifying as a termination event as described in the Protocol

20.2 Upon the effective date of termination, the Principal Investigator shall conduct an accounting review which is subject to verification by SIRO. If SIRO objects to any charges, the parties shall use reasonable efforts to resolve expeditiously any disagreement within thirty (30) days upon receipt of adequate documentation therefor. SIRO will make payment to the Institution for

20.2.1 all services properly rendered and monies properly expended by the Principal Investigator and/ or SMO prior to the date of termination and not yet paid for, and

20.2.2 reasonable non-cancelable obligations properly incurred for the Clinical Study by the Principal Investigator prior to the effective date of termination

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20.3. The Principal Investigator and/ or SMO will credit or return to SIRO any funds not expended or obligated by the Principal Investigator in connection with the Clinical Study prior to the effective termination date

20.4 Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Clinical Study and shall cease conducting procedures on Subjects already enrolled in the Protocol as directed by SIRO to the extent medically permissible and appropriate

20.5. Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination The rights and duties under Sections 4 2,8 2,9, 10, 12 2 and 18 survive the termination or expiration of this Agreement.

21. Miscellaneous

21 1 **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. Notwithstanding the foregoing,SPONSOR may seek injunctive or equitable relief, in addition to damages, for a breach of any of the confidentiality provisions contained herein in any court of competent jurisdiction.

21.2 All disputes arising out or in connection with the present Agreement, which cannot be settled amicably, shall be referred to and settled by sole arbitrator The proceedings will be governed by the Indian (Arbitration & Conciliation) Act, 1996 The place of the arbitration shall be Mumbai and the language of the arbitration proceedings shall be English Any judgment, decision or award of the arbitrators shall be final and binding on both the Parties, and shall be enforceable in any court of competent jurisdiction

21.3 Subject to 21.2 above the courts of Mumbai will have exclusive jurisdiction to try and entertain any dispute arising out of this Agreement.

21 4 The parties shall share equally the costs of the Board of Arbitration unless the Board determines otherwise.

21 5 **Amendments.** This Agreement may only be amended by the mutual written consent of the parties hereto

21.6 **Entire Agreement.** This Agreement represents the entire understanding of the parties with respect to the subject matter of this Agreement and supercedes all prior agreements, undertakings negotiations and discussions, whether oral or written between the parties and there are no warranties condition, representations or other Agreements between the parties in connection with the subject matter of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall be one document binding on all the parties even though each of the parties may have signed different counterparts This Agreement shall also be considered executed by the parties upon receipt by SIRO by facsimile transmission of the counterparts signed by all the parties

21 7 **Severability.** Should one or more provisions in this Agreement be or become invalid or unenforceable the Parties shall substitute such invalid provisions by valid provisions as close in meaning and effect as the original provisions Should such substitution not be possible the invalidity or unenforceability of such provision shall not affect the validity of the Agreement as a whole

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21.8 **Assignment.** The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of SIRO.SIRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates

21.9 **Waiver.** Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every provision of this Agreement.

21.10. **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:

If to Principal Investigator:

Dr Jyothi Hattitholi
Consultant Chest Physician
KLES Dr Prabhakar Kore Hospital & MRC
Nehrunagar Belagavi-590010 Karnataka India

If to INSTITUTION:

Dr M.V. Jali
Medical Director & CEO
KLES Dr Prabhakar Kore Hospital & MRCNehrunagar Belagavi-590010
Karnataka India

If to SIRO:

Dr Ganesh Divekar
Head, Clinical Research & Medical Services
SIRO Clinpharm Pvt. Ltd
Kalpataru Prime, 1st Floor, Unit nos 3 and 4, Plot no D-3, Road no 16, Wagle Industrial Estate, Thane (West) – 400604, Maharashtra,INDIA

With a Copy to:

Maruti Patil
Managing Director
Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli,Belagavi –Karnataka India 590008

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in Quadripartite by proper persons thereunto duly authorized.

SIRO Clinpharm Pvt. Ltd

Signature _____ 04 Feb 2020

Name Dr Ganesh Divekar

Designation Head Clinical Research & Medical Services

INSTITUTION

Signature _____

Name Dr M V Jali

Designation MD & CEO

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

Date 04 Feb 2020

Date 25 Feb 2020

PRINCIPAL INVESTIGATOR

Signature:

Name. Dr Jyothi Hattiholi

Designation: Principal Investigator

Date: 12 Feb 2020

SMO(Doclin Clinical Research Services)

Signature:

Name Maruti Patil

Designation: Managing Director

Date 12 Feb 2020

EXHIBIT A: PROTOCOL

As annexure 1

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EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : *Dr Jyothi Hattitholi*

Site Address :KLES Dr Prabhakar Kore Hospital & Medical Research Centre. Belagavi- 590010 Karnatka India

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for patients is as follows

Overall Per Patient Budget

Amount in Indian rupees per patient	Reimbursement
INR 62,220 per patient.	Includes the following • PI and site team payment including Co Investigator (s), Site coordinator(s) • Local lab cost, Study related tests • Hospitalization cost (on basis of actual number of days of hospitalization per subject) • Institutional overhead 25% • Patient travel reimbursement as approved by the EC.

Budget Bifurcation

Visits	PI & CRC fees per Visit (INR)	IOH 25% (INR)	Lab + test charges (INR)	Hospitalization (per actual No of days)	Patient travel reimbursement (INR)	Total Payment Per Completed Patient (INR)
Screening / Placebo Run-in	6000	1500	5310	NA	NA	12,810
Period 1	6000	1500	NA	7000	500	15 000
Period 2	6000	1500	NA	7000	500	15,000
Period 3	6000	1500	4410	7000	500	19 410
Total	24 300	6 000	9 720	21 000	1500	62 220

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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] Study Study start up cost (Advance/ pre payment) INR. 50,000/-
The advance payment (pre payment) provided to the PI **will be adjusted against first two invoices** raised by PI as per the PI grant

The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion

2] CRO will pay only INR5000/- for 1 screen fail subject per site. 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] Archival fees CRO shall pay INR 90,000 per year towards archival of study documents for 15 years from time of site close out

4] IP Management fees of 30,000 per year

Payee Details

Payee Name (or institution)	Doclin Clinical Research Services
Payee Address	445,Maruti Galli, Main Road, Hangarge Mandoli Belagavi Karnataka,590008
Bank Name and Address	Axis Bank -Nehru Nagar, Ratna Plaza, Cts No 10593 A& B, Kolhapur Circle, Belgaum 590010
Cheque/Draft (in favor of)	Doclin Clinical Research Services
Account Number	919020049795418
PAN Card Number	AZXPP8818R

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GST Number	29AZXPP8818R1ZP
IFSC Code	UTIB0001690
Contact person for payments	Mr Maruti Patil

Payment Adjustments

If Institution s/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator / SMO 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

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 fourty five (45) days after the receipt of final payment to dispute any reasonable payment discrepancies

Invoices:

Send invoices to Siro Clinpharm Pvt Ltd Contact Person Study PM

Address Siro Clinpharm Pvt Ltd
Kalpataru crime
1st floor, Units 3 and 4 Plot D3 Road 16
Wagle industrial estate Thane west 400604

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Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

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 manager, 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 specific visits. 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. 20 % of the total amount for one randomized patient only i.e. INR 12424/- 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
6. A tax of 10% will be deducted in case a tax exemption certificate is not provided. This tax amount has been calculated and added to total grant amount. In case a tax exemption certificate is provided, then the tax amount (@ 10%) will not be applicable to be released to the site in the budget.
7. A GST (as applicable) will be considered on total grant subject to availability of GST registration number with service provider GST will be paid and applicable to service provider, provided the GST registration number is reflected on Invoice / Bills "
8. 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

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K L E VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES
(A Constituent unit of KLE Academy of Higher Education & Research
(Formerly known as KLE University) Deemed-to-be-University u/s 3 of the UGC Act, 1956)
J.N.M.C. Campus, Nehru Nagar, Belagavi-590 010, Karnataka, India
Accredited 'A' grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

1	Name of the program	Tobacco Awareness
2	Program /camp organized by (dept)	Dept of Oral Medicine and Radiology
3	Department /association	KLE Vishwanath Katti Institute of Dental Sciences, BelagaviDept of Oral Medicine and Radiology
4	Date of conduct of the program/camp	29/01/20
5	Duration of the camp/program	3 hour
6	location	CIJW ITBP Halabhavi
7	Objectives of the program/camp	Tobacco awareness and dental check up
8	Chief guest and dignitaries present	———
9	Name of the external member of the attended program/camp/special camp	———
10	Activities carried out during the program	Lecture delivered on Tobacco illeffects and its cessation. Oral hygiene instructions
11	No of nss volunteer present/involved	15
12	No of benefacieries benefited from the camp	300
13	photographs	Yes
14	Press clippings	No
15	Any other relevant information	--

PRINCIPAL
KLE V.K. Institute of Dental Sciences
Nehru Nagar, BELAGAVI-590010

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-KA63922188269041R
Certificate Issued Date	:	19-Dec-2019 11:10 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BELGAUM27/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08437683461960 33R
Purchased by	:	PRINCIPAL KLE VKIDS BELAGAVI
Description of Document	:	Article 4 Affidavit
Description	:	AFFIDAVIT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PRINCIPAL KLE VKIDS BELAGAVI
Second Party	:	DIG CIJW SCHOOL ITBP BELAGAVI
Stamp Duty Paid By	:	PRINCIPAL KLE VKIDS BELAGAVI
Stamp Duty Amount(Rs.)	:	50 (Fifty only)

Authorised Signatures
Sadhar Multi-Purpose Souhard Sahakari
Nyt. Shivabasav Nagar, BELAGAVI

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

Between

KLE VK Institute of Dental Sciences, Belagavi

AND

ITBP Training Centre, Halabhavi Camp, Vantamuri

ATTESTED

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

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This Memorandum of Understanding (MoU) is signed between the KLE Vishwanath Katti Institute of Dental Sciences, Belagavi as of represented by KLE VKIDS, Belagavi as First Party and CIJW School, ITBP , Halabhavi Camp, Vantamuri, Tal: Belagavi as Second Party for a period of Five (5) years with effect from the date of signing this MoU, for providing Free Dental Check-up and Oral Health Education and awareness as per the confirmed program and finalization of date, time and place.

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi shall conduct Free Dental Check-up. Oral Health Education, Lecture on Ill-effects of Tobacco for staff, trainees and family members of ITBP Training Centre, Halabhavi Camp, Vantamuri, Tal: Belagavi. The above mentioned activities will be conducted as per the convenience of Party I and Party II.

The officials of ITBP Training Centre, Halabhavi Camp, Vantamuri, Tal: Belagavi shall look after the local logistic support which includes well-lit room, Tables, Chairs, Audio-visual aids, electrical points, manpower (if required) etc. for smooth conduct of the camp. If the duration of the camp is more than 2 hours the Party II shall provide beverages and if the camp is more than 3 hours duration than Party II shall provide basic hospitality.

The services to be rendered by Party I shall be imparted by the Staff, Postgraduate students, Interns of KLE VKIDS, Belagavi.

Party I (KLEVKIDS) shall provide with:-

I. For Dental Check-up :-

1. All instruments and consumable required.

ATTESTED

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

2. Free Dental Check-up for all those who attend the camp as per the schedule notified.
3. Patients who need treatment will be referred to KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi and free treatment will be provided for all primary procedures like simple extractions, fillings, scaling and complete denture. Specialized treatment like surgical procedures, RCT, prosthesis work (other than complete dentures) etc, will be provided 50% concession. Concession is not admissible for specialized treatments like dental implants, orthodontics, veneers and laboratory work.
4. Brochures, Pamphlet, Display Poster, Charts, etc. necessary for camp will be provided.

II. **For Educational Camps:-**

Awareness lectures with Power Point Presentation on

i) Oral Hygiene,

ii) Ill-effects of tobacco will be given in Hindi / English language.

III. **For Blood Investigation :**

Free estimation of Hemoglobin, Basic Blood Grouping & Random Blood Sugar investigation will be done at the camp.

Party I (KLE VKIDS) shall have the privilege of compiling the data and using the observations for scientific research work and publication. This shall be done only after obtaining written consent in language known to the consenting patient / person before publishing any data. The identity of the patient / person and Party II shall be always kept confidential.

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

Publicizing of the camp conducted as per prior scheduled program by Party II shall be done with consent of Party I.

This MoU shall have no financial implications on either of the Parties (I & II). Any payment received towards treatment or investigations shall be noted and receipt for the received amount shall be given to the patient / person concerned.

This MoU is being signed by the Head of the Institution – Principal (Party I, KLE VKIDS) and Deputy Inspector General of Police of the CIJW School, ITBP , Halabhavi Camp, Vantamuri, Tal: Belagavi along with the witness specified as under.

This MoU has been duly signed as on 02/01/2020 by the representatives of Party I and Party II.

Sign & Date:

Dr. Alka D Kale
Principal
KLE VKIDS, Belagavi

02.1.2020.
DIG, CIJW School,
ITBP , Halabhavi Camp,
Vantamuri, Tal: Belagavi

Witness

1) **Dr. Vaishali Keluskar**
Professor, Dept. of OMDR
KLE VKIDS, Belagavi

2) **Dr. Anil Ankola**
Prof. & Head
Dept. of Public Health Dentistry
KLE VKIDS, Belagavi

Witness

1)
Adjutant, CIJW School ,
ITBP, Halbhavi Camp, Belagavi

2) **Dr. Mohit Sharma**
SMO, CIJW School ,
ITBP, Halbhavi Camp, Belagavi

Date : 02/01/2020
Place : Belagavi

ATTESTED

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

KLE SCHOOL

MEMORANDUM OF UNDERSTANDING

This memorandum of understanding is signed between the KLE V.K Institute of Dental Science, Belagavi and KLES' International School, Belagavi for a period of five years for providing free dental care to our staff and students.

Principal
Mrs.Dipti Ingley
PRINCIPAL
KLE INTERNATIONAL SCHOOL, BELAGAVI

KLE International School Belagavi

Date: 23/08/2019

KLES' International School
Scheme No. 40, Kuvempu Nagar, Hindalaga, Belagavi - 591108
Affiliated to CBSE, New Delhi, Affln No: 830229
Ph: 0831 - 2466281 E-mail: klesisbgm@yahoo.co.in Website: kleschoolbelgaum.com

ATTESTED

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

Affiliated to CBSE New Delhi vide no. 830406

Sahakar Education And Social Welfare Society's

Shivshankar Jolle English Medium Public School

Chikodi-Examba Road, Nanadi Campus, Nanadi - 591 244
Tal. Chikodi Dist. Belagavi Ph. 08338-276855, Mobile - 9663376807
e-mail : ssjcbse@gmail.com, website- www.ssjcbse.org

Ref. No: SSJEMPS/2019-20/164

Date: 31/08/2019

Memorandum of Understanding

This Memorandum of understanding is signed between the KLE's V.K. Institute of Dental Science, Belagavi and Shivashankar Jolle English Medium Public School, Nanadi for period of five years for providing free dental care to our staff and students.

31/8/19

Mrs. Geeta Naidu
Principal
Shivashankar Jolle English Medium
Public School, Chikodi - Examba Road
Nanadi Belgaum, Karnataka - 591244
Aff. No. 830406 School Code. 45351
Email: principalssjcmps@gmail.com Mob:-9553376207

ATTESTED

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

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By Hand

कार्यालय पुलिस महानिरीक्षक
सी.एस.जे.डब्ल्यु.टी., केरिपुबल
बेलगाँव, कर्नाटक - 591345

O/O THE INSPECTOR GENERAL
OF POLICE, CSJWT, CRPF,
BELGAUM, KARNATAKA- 591345

Control Room M/No- 09482584659
Email. id-csjwtbgm@crpf.gov.in

No.M-III-1/2020-EC-IV

Dated, the 16 March., 2020

To,

Dr. Alka D. Kale,
Principal, KLE VKIDS,
Belagavi, Karnataka.

Sub:- **Forwarding of MoU between KLE VK Institute of Dental Science, Belagavi and CoBRA School of Jungle Warfare & Tactics (CSJWT), Torali, Belagavi.**

Madam,

Memorandum of Understanding (MoU) for five years between KLE VK Institute of Dental Science, Belagavi and CoBRA School of Jungle Warfare & Tactics (CSJWT), Torali, Belagavi for free dental check-up and Oral health education and awareness and also 50% concession other than complete dentures is forwarded to your office in duplicate after signature of the IGP/Principal, CSJWT, CRPF, Belgaum for information and further needful action please.

Encl: (Original MoU in Two copies)

16/3/2020

(Gaurav Kumar), 2-I/C
For IGP, CSJWT, CRPF

Medical Officer, CSJWT, CRPF, Belgaum alongwith a copy of MoU for information and needful.

File

ATTESTED

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

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सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA831293636429005
Certificate Issued Date	:	14-Jan-2020 04:58 PM
Account Reference	:	NONACC (FI)/ kaksicl08/ BELGAUM27/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08802033596494965
Purchased by	:	PRINCIPAL KLE VKIDS BELAGAVI
Description of Document	:	Article 12 Bond
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PRINCIPAL KLE VKIDS BELAGAVI
Second Party	:	IGP CSJWT CRPF
Stamp Duty Paid By	:	PRINCIPAL KLE VKIDS BELAGAVI
Stamp Duty Amount(Rs.)	:	50 (Fifty only)

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

Rs. 50

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

Between

KLE VK Institute of Dental Sciences, Belagavi

AND

Cobra School of Jungle Warfare & Tactics (CSJWT), Torali

ATTESTED

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

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This Memorandum of Understanding (MoU) is signed between the KLE Vishwanath Katti Institute of Dental Sciences, Belagavi as of represented by KLE VKIDS, Belagavi as First Party and Cobra School of Jungle Warfare & Tactics (CSJWT), Torali, Tal: Khanapur as Second Party for a period of Five (5) years with effect from the date of signing this MoU, for providing Free Dental Check-up and Oral Health Education and awareness as per the confirmed program and finalization of date, time and place.

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi shall conduct Free Dental Check-up, Oral Health Education, Lecture on Ill-effects of Tobacco for staff, trainees and family members of Cobra School of Jungle Warfare & Tactics (CSJWT), Torali. The above mentioned activities will be conducted as per the convenience of Party I and Party II.

The officials of Cobra School of Jungle Warfare & Tactics (CSJWT) , Torali shall look after the local logistic support which includes well-lit room, Tables, Chairs, Audio-visual aids, electrical points, manpower (if required) etc. for smooth conduct of the camp. If the duration of the camp is more than 2 hours the Party II shall provide beverages and if the camp is more than 3 hours duration than Party II shall provide basic hospitality.

The services to be rendered by Party I shall be imparted by the Staff, Postgraduate students, Interns of KLE VKIDS, Belagavi.

Party I (KLEVKIDS) shall provide with:-

I. For Dental Check-up :-

1. All instruments and consumable required
2. Free Dental Check-up for all those who attend the camp as per the schedule notified.

ATTESTED

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

3. Patients who need treatment will be referred to KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi and free treatment will be provided for all primary procedures like simple extractions, fillings, scaling and complete denture. Specialized treatment like surgical procedures, RCT, prosthesis work (other than complete dentures) etc., will be provided 50% concession. Concession is not admissible for specialized treatments like dental implants, orthodontics, veneers and laboratory work.
4. Brochures, Pamphlet, Display Poster, Charts, etc. necessary for camp will be provided.

II. For Educational Camps:-

Awareness lectures with Power Point Presentation for

i) Oral Hygiene,

ii) Ill-effects of tobacco will be given in Hindi / English language.

III. For Blood Investigation :

Free estimation of Hemoglobin, Basic Blood Grouping & Random Blood Sugar investigation will be done at the camp.

Party I (KLEVKIDS) shall have the privilege of compiling the data and using the observations for scientific research work and publication. This shall be done only after obtaining written consent in language known to the consenting patient / person before publishing any data. The identity of the patient / person and Party II shall be always kept confidential.

Publicizing of the camp conducted as per prior scheduled program by Party II shall be done with consent of Party I.

ATTESTED

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

This MoU shall have no financial implications on either of the Parties (I & II). Any payment received towards treatment or investigations shall be noted and receipt for the received amount shall be given to the patient / person concerned.

This MoU is being signed by the Head of the Institution – Principal (Party I, KLE VK IDS) and Inspector General of Police of the Cobra School of Jungle Warfare & Tactics (CSJWT), Torali along with the witness specified as under.

This MoU has been duly signed as on 05.03. 2020 by the representatives of Party I and Party II.

Sign & Date:

Dr. Alka D Kale
Principal,
KLE VKIDS, Belagavi

Dr. T Sekar
IGP,
CSJWT, CRPF, Torali

Witness

1) **Dr. Vaishali Keluskar**
Professor, Dept. of OMDR
KLE VKIDS, Belagavi

2) **Dr. Anil Ankola**
Prof. & Head,
Dept. of Public Health Dentistry
KLE VKIDS, Belagavi

Witness

1) **Dr. Rathod S. B.**
Medical Officer
CSJWT, Torali

2) **Shri Gaurav Kumar**
Second In Command,
CSJWT, Torali

Date: 05 / 03 /2020
Place: Belagavi

ATTESTED

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

K L E VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES
(A Constituent unit of KLE Academy of Higher Education & Research
(Formerly known as KLE University) Deemed-to-be-University u/s 3 of the UGC Act, 1956)
J.N.M.C. Campus, Nehru Nagar, Belagavi-590 010, Karnataka, India
Accredited 'A' grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

1	Nameoftheprogram	Oral checkup and tobacco awareness
2	Program /camporganizedby(dept)	Department of Oral Medicine And Radiology and department of Public Health Dentistry
3	Department /association	
4	Dateofconduct oftheprogram/camp	2/5/2019
5	Durationofthecamp/program	10.00am to 2.00 pm
6	location	COBRA school of jungle warfare and tactics Torali.
7	Objectivesoftheprogram/camp	To create awareness of ill effects of tobacco. dental check up
8	Chiefguestand dignitariespresent	
9	Name of the external member of the attended program/camp/specialcamp	
10	Activitiescarriedoutduring theprogram	Guest lecture on Ill effects of Tobacco and Tobacco cessation and dental check up
11	NoofNSS volunteerpresent/involved	8
12	Noofbeneficiariesbenefited from thecamp	120
13	photographs	
14	Pressclippings	
15	Anyotherrelevantinformation	

PRINCIPAL
KLE V.K. Institute of Dental Sciences
Nehru Nagar, BELAGAVI-590010

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

MEMORANDUM OF UNDERSTANDING

This MEMORANDUM OF UNDERSTANDING (hereinafter referred to as the "MOU") is entered into this the 9th day of December, 2019 at Belagavi by and between

....2

ATTESTED

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

BETWEEN:

Regenta Resort by Royal Orchids
Situated at: # 140/1,
Belagavi-Jamboti Road, SH 54,
Belagavi, Karnataka-590014
Represented by Its General Manager
Mrs Nimmy Das

(Which expression shall unless repugnant to the context or meaning thereof, be deemed to mean and include her successors in office and permitted assigns)
HEREINAFTER referred to as **REGENTA**

AND

KLE Academy of Higher Education and Research
Represented by
The Registrar
Dr (Prof) V A Kothiwale
Situated at JNMC Campus,
Nehru Nagar, Belagavi-590010.

(Which expression shall unless repugnant to the context or meaning thereof, be deemed to mean and include his successors in office and permitted assigns)

HEREINAFTER referred to as **KAHER**

WHEREAS REGENTA is a Resort managed by Royal Orchids & Regenta Hotels engaged in providing hospitality services in and around Belagavi. REGENTA is desirous to establish a professional relationship with KAHER to engage with students to bridge the gap between hospitality theory and industry practice.

WHEREAS KAHER is a deemed-to-be University established u/s 3 of the UGC Act 1956. KAHER has started a course in B.Sc Hotel

...3

ATTESTED

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

Management and Catering Technology under the Department of Allied Courses.

FURTHER KAHER is willing to partner with REGENTA to create a platform for its students through which they can directly interact with industry experts and can learn from their live experiences. The objective is to facilitate learning and development for students and faculty members by utilizing REGENTA"s international hospitality expertise. The students are enabled with the latest developments in the hospitality domain.

NOW THEREFORE, in consideration of mutual assurances and undertaking herein contained, the parties agree as follows:

Term and Termination of this MOU:

1. This MOU shall remain in force for a period of 12 months from 09th December 2019 upto 08th December 2020 and may be extended for a further period of 12 month by mutual consent.

2. This MOU is at will and may be modified by mutual consent of both the parties on a prior notice of one month.

3. Subject to the provisions of this MOU, either party may terminate this MOU with or without cause, by giving Sixty (60) days written prior notice to the other party.

Obligations of FFBM

1. REGENTA shall visit KAHER HMTC (Institute of Hotel Management & Catering Technology) periodically and interact with students.

2. REGENTA shall provide internship opportunities to deserving students of KAHER-HMTC

....4

ATTESTED

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

3. REGENTA shall assist the institute by providing subject matter experts for conducting Guest lecturers, counseling sessions and Career talks with the students.

4. REGENTA shall plan structured immersion programme (theory & experimental) for meritorious students at their location for mutually agreed duration during weekends and to be jointly certified by both the parties at the end of the programme.

5. It shall provide opportunities for faculty members of KAHER to partner in joint research initiatives, and research paper publications.

6. REGENTA shall depute its specialists as external examiner

7. Further it shall provide industry exposure to faculty members by organizing visits to REGENTA.

8. They shall conduct management development and faculty development programs and support student and faculty mentorship.

9. Participate in mock interview drive to help students prepare for recruiting by conducting one-on-one interviews or sharpening their interviewing skills.

10. REGENTA shall partner with KAHER for its CSR/Sustainable Development initiatives like Swatch Bharat etc.,

11. They shall participate and support KAHER during fests, seminars, workshops and conferences based on mutual agreeable terms.

....5

ATTESTED

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

Obligations of KAHER

1. KAHER shall dedicate a Notice Board in HMCT campus to REGENTA named as *"Hotel's Corner"* wherein REGENTA will display all the communications, information, highlights, success stories, events and achievements etc, pertaining to them.

2. KAHER shall acknowledge and highlight the support provided by REGENTA through its communication platforms such as Hotels School Magazines, article in Print Media etc and shall seek prior approval of REGENTA.

3. It shall treat REGENTA as a preferred employer for campus interview drives (placements/Industrial Exposure) and shall be invited in first three companies to visit the campus.

4. Further it shall provide refresher programme and soft skill certifications for REGENTA.

5. KAHER shall provide columns in KAHER'S newsletter and other publications to REGENTA to share its expert commentaries.

WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers or representatives on the date and place first mentioned above.

ATTESTED

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

Contact Information

Regenta Resorts by Royal Orchids	KLE Academy of Higher Education and Research
General Manager #140/1, Belagavi-Jamboti Road SH 54, Belagavi-590014	Office of the Registrar JNMC Campus, Nehru Nagar, Belagavi 590010.

Signed by

Mrs. Nimmy Das
General Manager
Regenta Resorts

Signed by

Prof. Dr. V. A Kothiwale
Registrar
KLE Academy of Higher
Education & Research

BELAGAVI
DATED: 09.12.2019

ATTESTED

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

MEMORANDUM OF UNDERSTANDING

This MEMORANDUM OF UNDERSTANDING (hereinafter referred to as the "MOU")is entered into this the 7th day of December, at Belagavi 2019 by and between

....2

ATTESTED

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

BETWEEN:

Fairfield by Marriott
(A unit managed by Marriott International)
Located at Gogte Plaza,
Belagavi, Karnataka-591113
Represented by Its General Manager
Mr Vinayak Patnekar

(Which expression shall unless repugnant to the context or meaning thereof, be deemed to mean and include his successors in office and permitted assigns)

HEREINAFTER referred to as **FFBM** .

AND

KLE Academy of Higher Education and Research
Represented by
The Registrar
Dr (Prof) V A Kothiwale
Situated at JNMC Campus,
Nehru Nagar, Belagavi-590010.

(Which expression shall unless repugnant to the context or meaning thereof, be deemed to mean and include his successors in office and permitted assigns)

HEREINAFTER referred to as **KAHER**

WHEREAS FFBM is a star hotel managed by Marriott International engaged in providing hospitality services in and around Belagavi. FFBM is desirous to establish a professional relationship with KAHER to engage with students to bridge the gap between hospitality theory and industry practice.

WHEREAS KAHER is a deemed-to-be University established u/s 3 of the UGC Act 1956. KAHER has started a course in B.Sc Hotel Management and Catering Technology under the Department of Allied Courses.

....3

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

FURTHER KAHER is willing to partner with FFBM to create a platform for its students through which they can directly interact with industry experts and can learn from their live experiences. The objective is to facilitate learning and development for students and faculty members by utilizing FFBM's international hospitality expertise. The students are enabled with the latest developments in the hospitality domain.

NOW THEREFORE, in consideration of mutual assurances and undertaking herein contained, the parties agree as follows:

Term and Termination of this MOU:

1. This MOU shall remain in force for a period of 12 months from 07th December 2019 upto 06th December 2020 and may be extended for a further period of 12 month by mutual consent.

2. This MOU is at will and may be modified by mutual consent of both the parties on a prior notice of one month.

3. Subject to the provisions of this MOU, either party may terminate this MOU with or without cause, by giving Sixty (60) days written prior notice to the other party.

Obligations of FFBM

1. FFBM shall visit KAHER HMTC (Institute of Hotel Management & Catering Technology) periodically and interact with students.

2. FFBM shall provide internship opportunities to deserving students of KAHER-HMTC

3. FFBM shall assist the institute by providing subject matter experts for conducting Guest lecturers, counseling sessions and Career talks with the students.

4. FFBM shall plan structured immersion programme (theory & experimental) for meritorious students at their location for mutually agreed duration during weekends and to be jointly certified by both the parties at the end of the programme.

....4

ATTESTED

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

5. It shall provide opportunities for faculty members of KAHER to partner in joint research initiatives, and research paper publications.

6. FFBM shall depute its specialists as external examiner

7. Further it shall provide industry exposure to faculty members by organizing visits to FFMB.

8. They shall conduct management development and faculty development programs and support student and faculty mentorship.

9. Participate in mock interview drive to help students prepare for recruiting by conducting one-on-one interviews or sharpening their interviewing skills.

10. FFBM Partner with KAHER for its CSR/Sustainable Development initiatives like Swatch Bharat etc.,

11. They shall participate and support KAHER during fests, seminars, workshops and conferences based on mutual agreeable terms.

Obligations of KAHER

1. KAHER shall dedicate a Notice Board in HMCT campus to FFBM named as *"Hotel's Corner"* wherein FFBM will display all the communications, information, highlights, success stories, events and achievements etc, pertaining to them.

2. KAHER shall acknowledge and highlight the support provided by FFBM through its communication platforms such as Hotels School Magazines, article in Print Media etc and shall seek prior approval of FFBM.

3. It shall treat FFBM as a preferred employer for campus interview drives (placements/Industrial Exposure) and shall be invited in first three companies to visit the campus.

4. Further it shall provide refresher programme and soft skill certifications for FFBM.

....5

ATTESTED

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

5. KAHER shall provide columns in KAHER'S newsletter and other publications to FFBM to share its expert commentaries.

WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers or representatives on the date and place first mentioned above.

Contact Information

Fairfield by Marriot General Manager Gogate Plaza Belagavi-591113	**KLE Academy of Higher Education and Research** Office of the Registrar JNMC Campus, Nehru Nagar, Belagavi 590010.

Signed by

Mr. Vinayak Patnekar
General Manager
Fairfield by Marriot

Signed by

Prof. Dr. V. A Kothiwale
Registrar
KLE Academy of Higher
Education & Research

ATTESTED

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

ATTESTED

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

COLLABORATION AGREEMENT

This Collaboration Agreement (hereinafter referred to as the "Agreement"), effective as of 20th March, 2019 (hereinafter referred to as the "Effective Date"), entered into by and between

KAHER Academy of Higher Education and Research (KAHER), Belagavi, having its registered office at JNMC Campus, Nehru Nagar, Belgaum, Karnataka 590010, India (hereinafter referred to as "**KAHER**")

And

GE India Industrial Private Limited, a company incorporated and existing under laws of India, having its registered office address at 401, 402, 4th Floor, Aggarwal Millennium Tower, E-1, 2, 3, Netaji Subhash Place, Wazirpur, New Delhi 110034, an affiliate of General Electric Company (hereinafter referred to as "**GE Healthcare**")

(each individually hereinafter referred to as a "Party" and collectively hereinafter referred to as the "Parties").

ATTESTED

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

RECITALS

WHEREAS, GE Healthcare is, *inter alia*, engaged in, among other things, the development, manufacture and sale of diagnostic imaging systems (including, but not limited to, X-ray, Ultrasound, Computed Tomography, Molecular Imaging and Magnetic Resonance) and artificial intelligence enhanced software features and applications for medical systems and is in need of clinical data (such as, for example, clinical images, DICOM data, raw scan data, photographs, video cine loops, curated reports, patient vital data, clinical case studies; and/or corresponding physician reports, including but not limited to any associated metadata, annotations, waveforms, EMR text, pathology data, associated relevant clinical case patient data and customized protocols) (referred to herein as "**Data**") for use in connection with one or more of the following purposes: (i) internal and external technology and product development, including technology and product development of third parties with whom GE Healthcare may enter into agreements, (ii) internal and external education and training, (iii) marketing and product documentation, (iv) incorporation into a commercial product and (v) regulatory submissions; and accordingly has implemented a cloud-based infrastructure of big data platform including tools for cataloging, indexing, curating data and other tools for learning and computing for healthcare research which GE Healthcare may add from time to time at its sole discretion (referred to herein as "**Platform**");

WHEREAS, KAHER is interested in leveraging the Platform and is willing to upload and store Data on the Platform;

WHEREAS, GE Healthcare is willing to provide access to KAHER to the Platform in accordance with the terms and conditions of this Agreement; and

WHEREAS, GE Healthcare desires to collaborate with KAHER for contribution to the creation, testing, and implementation or transformational innovation within the healthcare field, aimed at improving the quality and efficiency of patient care;

WHEREAS, KAHER may assist in states of the product development process, including discovery/observational research of clinical workflow and user needs; image curation/annotation; product design feedback; and/or algorithm validation; and

WHEREAS, KAHER and GE Healthcare are willing to collaborate as described herein.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable considerations, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions.

a. Data" means one or more of the following types of clinical data from users of systems such as X-ray, Ultrasound, Computed Tomography, Molecular Imaging and Magnetic Resonance: (i) clinical images, (ii) raw scan data, (iii) clinical case studies, (iv); and/or (iv) corresponding radiologist reports, including but not limited to any associated metadata, annotations, waveforms, EMR text, pathology data, and associated relevant clinical case patient data.

b. "**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996 Pub.No. 104-191 ("**HIPAA**") and its implementing regulations, the Standards for Privacy of Individually Identifiable Health Information (the "**Privacy Rule**") and the Security Standards for the Protection of Electronic Protected Health Information (the "**Security Rule**").

c. "**HITECH Act**" means Division A, Title XIII of the American Recovery and Reinvestment Act of 2009, subtitled the Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5 and its implementing regulations.

d. "**Intellectual Property**" means inventions, discoveries, concepts, ideas, data, improvements, combinations, extensions, computer software (source code and object code), methods, processes, machines, manufactures, compositions of matter, algorithms, original works of authorship, designs, prototypes, trademarks, trade secrets, and all related know-how, whether or not protectable under the patent, copyright, and/or trade secret laws of any applicable jurisdiction.

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e. "Privacy Laws" means privacy laws as applicable including, without limitation, HIPAA and the HITECH Act.

2. Scope of Agreement. GE Healthcare and KAHER will collaborate for KAHER to utilize the Platform, for the provision of De-identified (as defined in Section 3) Data by KAHER to GE Healthcare and to further the clinical development of healthcare applications. This Agreement contemplates access of the Platform by KAHER to upload and store De-identified Data created, received, accessed or maintained by KAHER in a standard of care/routine/non-research setting; and assistance in product development process as defined in one or more Statement (s) of Work (each, an "SOW") in the format set out in **EXHIBIT A**. Each Statement of Work shall incorporate by reference the terms of this Agreement. Unless otherwise expressly stated otherwise in a relevant SOW, in the event of any conflict between an SOW and this Agreement, the terms of this Agreement shall control.

3. Provision of Data by KAHER; Receipt of Data by GE Healthcare.

a. From time to time during the Term of this Agreement (as described in Section 16), KAHER shall upload and store Data onto the Platform from one or more of its sites/facilities described in Appendix A. KAHER undertakes that any Data it uploads and stores on the Platform has been de-identified in accordance with the requirements of applicable privacy, data and patient protection laws such that the Data no longer identifies the patient who is the subject of the Data and does not include "personal data", "personal information" or "sensitive personal data or information" (including any information about health status, provision of health care, or payment for health care or any other information that can be linked to a specific individual) which would result in the disclosure of their identity as defined under applicable laws and regulations ("**De-Identified**"). Some GE Healthcare products include an automated de-identification tool or function; however, GE Healthcare makes no representation or warranty that such tool or function will render Data De-Identified. KAHER undertakes to comply with all applicable laws and guidelines, to obtain all required approvals (including EC approval if applicable) and to inform patients whose De-Identified Data is transferred and stored on the Platform about the De-Identification, transfer to, and use of, such Data by GE Healthcare as described in Section 4 below. Where required pursuant to applicable law, KAHER shall obtain the required consent of persons whose De-Identified Data is uploaded and stored on the Platform and use of, such Data by GE Healthcare. The consent proceedings should be audio/video recorded as per guidelines from CDSCO (Central Drugs Standard Control Organization), if applicable. KAHER represents and warrants that it has and shall continue to have perpetual rights, ownership and interest in Data transferred and stored on the Platform and to provide GE Healthcare the rights to use the Data as specified in Section 4 below. With respect to Data transferred and stored on the Platform that GE Healthcare knows or suspects is not De-Identified, GE Healthcare reserves the right, in its sole discretion, to either (i) reject and securely destroy or return such Data to KAHER, or (ii) de-identify such Data and securely destroy or return to KAHER the original version that was not De-Identified. The terms and conditions set forth in **Exhibit B** ("**Terms of Use**") and incorporated by reference into the Agreement shall govern the access and use of the Platform by the KAHER.

b. GE Healthcare shall take no action that would result in re-identification or misrepresentation of Data, and the appropriate attribution of the Data will be done so as not to re-identify or misrepresent the Data.

4. Data License. KAHER grants to GE Healthcare and Affiliates a non-exclusive, worldwide, perpetual, irrevocable, royalty-free right and license, including the right to sublicense, to use, copy, reproduce, alter, incorporate, modify (which in the case of raw data includes image reconstruction from the raw data) and display the Data, in whole or in part, and to create derivative works based thereon, in connection with one

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or more of the following purposes: (i) internal and external technology and product development, including technology and product development of third parties with whom GE Healthcare may enter into agreements, (ii) internal and external education and training, (iii) marketing and product documentation, (iv) incorporation into a commercial product and (v) regulatory submissions, all of which may involve disclosure to third parties with which GE Healthcare has contracted to assist with such activities. This Data License shall survive the Termination of this Agreement as described in Section 16. Derivative works shall be considered Collaboration Work Product as described in Section 9. KAHER represents and warrants that KAHER has and will have good and marketable title to, or the right to license Data licensed hereunder. "**Affiliate**" means any entity that directly or indirectly, controls, is controlled by, or is under common control with a party.

5. Use by KAHER. In the event GE Healthcare processes, the Data to catalog and index the Data ("**Processed Data**"), GE Healthcare shall grant to KAHER a non-exclusive, worldwide, royalty-free license to the Processed Data.

6. Research Infrastructure. KAHER undertakes that any research it conducts using the tool of the Platform is conducted in accordance with the requirements of applicable privacy, data and patient protection laws. With respect to healthcare research tools provided hereunder that GE Healthcare knows, or suspects is misused, GE Healthcare reserves the right, in its sole discretion, to either (i) revoke access to the tools, or (ii) securely un-provision the infrastructure for the KAHER.

7. Infrastructure for Data Transfer. KAHER and GE Healthcare shall mutually coordinate for deployment of the IT infrastructure for the transfer of Data from the sites/facilities of KAHER to the Platform. In the event any hardware is provider by GE Healthcare to KAHER for the transfer of the Data to the Platform, such hardware shall be temporarily loaned to KAHER by GE Healthcare. KAHER shall return the hardware to GE Healthcare promptly upon termination of this Agreement. GE Healthcare shall keep title in the hardware during the term of the Agreement. The KAHER will preserve GE Healthcare's title in the hardware free and clear of all claims, encumbrances and liens. The KAHER will not transfer custody of the hardware to a third party.

8. GE Healthcare Resources. GE Healthcare, in its sole discretion, may permit KAHER to have on-line access to GE-designated networks and computer systems of GE Healthcare ("GE Healthcare Resources") in order to facilitate KAHER's ability to perform its obligations to GE Healthcare under this Agreement. The term "GE Healthcare Resources" also includes all information obtained, stored, or accessible on such networks and systems. If such access is granted, KAHER will promptly give GE Healthcare in writing the names of KAHER's employees who have a legitimate business need for such access to GE Resources ("Authorized Personnel"), and GE will provide a separate user identification code for each person ("Password"). Only Authorized Personnel may access and use GE Healthcare Resources. Authorized Personnel will access and use GE Healthcare Resources solely for the purpose of fulfilling KAHER's obligations to GE Healthcare under this Agreement ("**Permitted Use**"). Passwords and GE Healthcare Resources are provided on an "AS-IS" basis and constitute GE Healthcare's Confidential Information. GE Healthcare, in its sole discretion, may
9. terminate with or without cause KAHER's and/or any Authorized Personnel's access to GE Healthcare Resources at any time. KAHER, including Authorized Personnel, will: (i) comply with all instructions GE Healthcare provides concerning access to GE Healthcare Resources; (iii) not modify, copy, store, transfer, install, delete or obtain programs or data from GE Healthcare Resources, unless GE Healthcare has expressly authorized KAHER to do so in advance and in writing; (iv) not cause GE Healthcare to incur fees or service charges; and (v) not change the configuration or topology of GE Healthcare Resources. KAHER, including Authorized Personnel, will immediately cease accessing all GE Healthcare Resources upon the earliest to occur: (a) when no longer required to perform work under this Agreement; (b) when notified by GE Healthcare; or (c) when this Agreement terminates or expires. KAHER will immediately notify GE Healthcare if it becomes aware of any unauthorized access to or use of GE Healthcare Resources, and will instruct Authorized Personnel to do the same. Any document properly transmitted by computer access will be considered as "writing" delivered in connection with this Agreement. Electronic documents will be

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considered signed by a party if they contain an agreed upon electronic identification symbol or code as required by law. Electronic documents will be deemed received by a party when accessible by the recipient on the computer system.

10. Intellectual Property. All Intellectual Property developed under this Agreement, whether individually or jointly developed by GE Healthcare and/or KAHER, or whether it is based upon, makes references to, incorporates or otherwise makes use of, in whole or in part, feedback and/or input given by KAHER (collectively, the "**Collaboration Work Product**"), shall be exclusively owned by GE Healthcare and KAHER hereby assigns to GE Healthcare its entire rights, title, and interest in and to the Collaboration Work Product. KAHER agrees that the Collaboration Work Product are works-made-for-hire for GE Healthcare under the U.S. Copyright Act (collectively, the "**Works**"), and as such shall be the sole and exclusive property of GE Healthcare, and GE Healthcare shall be deemed the author of the Works. In the event any such Work is not automatically owned by GE Healthcare as a work-made-for-hire under copyright law, KAHER hereby assigns to GE Healthcare its entire right, title and interest in and to such Work. KAHER further acknowledges and agrees, and shall ensure, that all moral rights which the KAHER, its employees or representatives involved in the performance of this Agreement may have in any copyrightable works of authorship are hereby waived and that the benefit of this waiver may be invoked by GE Healthcare or any assignee or licensee of any of such works from GE Healthcare. KAHER agrees to promptly execute any document required to secure such rights and to vest any such property legally in GE Healthcare or its nominee. For purposes of clarification, the Collaboration Work Product and the Works do not include, and GE Healthcare shall not own, any Intellectual Property which were developed by KAHER. independently of and unrelated to this Agreement (collectively, the "**KAHER Intellectual Property**"). To the extent KAHER incorporates any KAHER Intellectual Property into any Collaboration Work Product or Works, KAHER hereby grants GE Healthcare a perpetual, worldwide, royalty-free right to distribute, sublicense, copy, display, modify and otherwise utilize such KAHER Intellectual Property in connection with applicable Collaboration Work Product or Works. KAHER agrees to assist GE Healthcare to obtain and enforce United States and foreign patents, copyrights, and other rights and protections relating to any and all Collaboration Work Product and Works in any and all countries, provided that GE Healthcare shall reimburse KAHER for reasonable costs associated with providing such assistance. To that end, KAHER will execute, verify and deliver such documents and perform such other acts as GE Healthcare may reasonably request for use in applying for, obtaining, sustaining and enforcing such patents, copyrights, and other rights and protections on such Collaboration Work Product. KAHER represents and warrants that KAHER has and will have good marketable title to, or has the right to provide GE the Intellectual Property rights set out herein.

    a. Limited License. To the extent that it is necessary for KAHER to have access to or use certain GE Healthcare software (including in beta version) to perform its obligations under an SOW, GE Healthcare grants KAHER a non-exclusive, non-transferable, non-sublicensable, revocable and limited right to view, access, display and use for internal business purposes only in a non-production environment, such software in object code form only ("**Licensed Software**") and related documentation,, information and materials ("**Documentation**"), in any media, including electronic, during the term of the SOW. No license rights are granted, whether by implied license or otherwise, to KAHER, except as specifically provided in this Section.

    b. Restrictions. KAHER agrees that it will not, directly or indirectly, through any parent, subsidiary, affiliate, agent or other third party: i) sell, lease, loan, assign, license, sublicense, encumber or otherwise transfer the Licensed Software or Documentation, or use the Licensed Software or Documentation for any other purpose, except as expressly provided in Section 6(a), including for timesharing, rental or sharing arrangements, or on a "service bureau" basis, or otherwise use or allow use of the Licensed Software or Documentation for the benefit of any third party; ii) decompile, disassemble, translate or reverse engineer the Licensed Software or attempt to discover any source code or underlying ideas or algorithms thereof; remove, obscure or alter

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any product identification, trademark, copyright, confidentiality, proprietary or other notice contained on or within the Licensed Software or Documentation; or iii) modify or create any derivative works from the Licensed Software or any portion thereof. To the extent that KAHER creates any derivative works or its use of the Licensed Software results in any derivative works, GE shall own such derivative works

11. Compensation, Invoices, Payment. KAHER's compensation for provision of Data in accordance with the budget set forth in **Exhibit C** (**"Budget"**), attached hereto and incorporated herein. KAHER's compensation for the Collaboration Work Product to GE Healthcare hereunder, if any, will be set forth in an SOW. KAHER shall submit an invoice to GE Healthcare by no later than ninety (90) days after the achievement of each milestone set forth in an SOW. Invoices shall be paid by GE Healthcare at net one hundred twenty (120) days after receiving the invoice. Unless prohibited by law, KAHER will separately indicate on its invoices any applicable GST that is required at law to be imposed on the sale of Goods/Services, unless GE Healthcare has provided Licensor with valid exemption or resale certification/documentation. If goods and goods tax (GST) is applicable on the Goods/Services supplied by KAHER and invoiced to GE Healthcare, then KAHER shall file the required statutory GST returns with the authorities within the time prescribed by law, so as to enable GE Healthcare to avail appropriate input tax credit on the Goods/Services procured from KAHER. All KAHER invoices are governed solely by this Agreement and any applicable SOW; any pre-printed terms appearing on KAHER's invoices are hereby deemed null, void and of no effect. Any expenses incurred by KAHER in connection with this Agreement are the sole responsibility of KAHER and are not reimbursable by GE. No "service" charge or other similar form of additional charge shall be applied. KAHER shall be responsible for the payment of all taxes, together with all governmental filing related thereto, which arise out of KAHER's performance under this Agreement or as a result of compensation paid hereunder. KAHER understands that GE Healthcare may report payments or other transfers of value associated with this Study under applicable laws such as the Sunshine Act. In order to fulfill these reporting obligations, GE Healthcare may request information regarding the transfers of value in this Study.

12. Compliance. GE Healthcare and KAHER agree that (a) GE Healthcare has a bona fide business need to obtain Data and Collaboration Work Product from KAHER and that KAHER has the skill and expertise required to perform its obligations hereunder, and (b) compensation provided hereunder is solely for the provision of Data and Collaboration Work Product and has not been determined in a manner that takes into account the volume of value of any referrals or other business otherwise generated between the Parties, has been negotiated at arm's length, represents fair market value, and is not intended by either Party as an inducement for purchasing or arranging the purchase of any good or service between GE Healthcare, KAHER or any third person not a party to this Agreement, and (c) the Parties shall comply with all applicable laws and regulations including, without limitation, Privacy Laws, applicable anti-bribery laws and regulations, and if applicable Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994 of India.

13. Compliance with Laws and Privacy and Data Protection. To the extent appropriately applicable, Service Provider shall comply with **Attachment A** (Privacy and Data Protection), as attached hereto.

14. Ethics Committee (EC) Approval. If applicable, KAHER is responsible for obtaining and maintaining approval of an EC for the purposes of performing under this Agreement or an SOW and send to GE Healthcare any documentation regarding the EC approval or waiver. In case of withdrawal or modification of EC Approval, KAHER will promptly notify GE in writing.

15. Confidentiality.

(a) Obligations. In connection with this Agreement, each Party (a **"Disclosing Party"**) may disclose, make available or provide access to its Confidential Information to the other Party (**"Receiving Party"**). Receiving Party shall only use Confidential Information or Materials (as defined below) for the Purposes articulated in this Agreement. Except as specifically permitted in this Agreement or as required by law (with

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reasonable prior notice to the Disclosing Party to allow Disclosing Party a reasonable opportunity to seek a protective order or equivalent), Receiving Party shall not disclose any Confidential Information or Materials to any third party without the prior written consent of Disclosing Party. Receiving Party shall at all times keep the Confidential Information and Materials confidential and shall take all reasonable security precautions (and in any event at least as great as the precautions Receiving Party takes to protect its own comparable confidential information) to keep confidential and protect the Confidential Information and Materials from unauthorized access and use. References to Receiving Party or Disclosing Party shall be deemed to include their respective Affiliates. **"Confidential Information"** means information that the Disclosing Party designates as being confidential or which, under the circumstances surrounding disclosure, should be treated as confidential by the Receiving Party, and includes, without limitation: (i) information relating to Disclosing Party's customers, services, and strategic plans; (ii) Disclosing Party's business policies or practices; (iii) technical, financial, marketing, or other technical or business information or trade secrets of Disclosing Party (whether or not marked as "confidential"); and (iv) information received from third parties that Disclosing Party is obligated to treat as confidential. For the avoidance of doubt, Confidential Information shall not include the Data and the Processed Data provided under the respective licenses in this Agreement for the Purpose. Notwithstanding the foregoing, the Receiving Party shall have no obligations with respect to any information which: (i) is or becomes publicly available through no act of the Receiving Party in breach of this Agreement; (ii) was in the possession of the Receiving Party prior to its disclosure or transfer as evidenced by written documentation; (iii) is independently developed by the Receiving Party and the Receiving Party can so prove; or (iv) is received from another source without any restriction on use or disclosure. **"Materials"** means all tangible or written materials containing Confidential Information, including without limitation, written or printed documents, emails and attachments, electronic files, and computer disks, whether machine or user readable.

(b) Rights and Remedies. Receiving Party shall notify Disclosing Party immediately upon discovery of any unauthorized use or disclosure of any Confidential Information or Materials, or any other breach of this Agreement, and will cooperate with Disclosing Party in every reasonable way to help Disclosing Party regain possession of the Confidential Information or Materials and prevent their further unauthorized use. At Disclosing Party's request, Receiving Party shall promptly return all originals, copies, reproductions and summaries of Confidential Information or Materials or, at Disclosing Party's option, certify destruction. Receiving Party acknowledges that monetary damages may not be a sufficient remedy for unauthorized disclosure or use of the other party's Confidential Information or Materials and that Disclosing Party shall be entitled, without waiving any other rights or remedies, to seek injunctive or equitable relief.

16. No Transfer of Rights; No other Warranty. Except for the rights granted in Sections 4, 5, 6, 7, 8 AND 9 above, no transfer or grant of rights under any patents, copyrights or other intellectual property rights is made or to be implied by any provision of this Agreement. Nothing in this Agreement shall be construed as precluding either Party from at any time independently developing ideas, negotiating with, or entering into any agreement with others relating to the general subject matter of this Agreement; subject, however, to the provisions of sections of this Agreement with respect to disclosure of Confidential Information. Nothing in this Agreement shall grant KAHER the right to directly or indirectly use or refer to the trademarks or trade name of GE or trade names similar thereto, without the written consent of GE Healthcare. EXCEPT AS EXPRESSLY PROVIDED HEREIN, NO OTHER EXPRESS OR IMPLIED WARRANTIES OR CONDITIONS, INCLUDING IMPLIED WARRANTIES OR CONDITIONS OF NON-INFRINGEMENT, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SYSTEM INTEGRATION AND DATA ACCURACY, WILL APPLY.

17. Term and Termination. The Term of this Agreement shall commence upon the Effective Date and shall continue in effect for a period of three (3) years, unless terminated earlier in accordance with this Agreement. Upon expiration or termination of this Agreement, the terms of this Agreement shall survive for

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purposes of any SOW that is still in effect, provided that each SOW may be terminated according to its own terms. Either Party may terminate this Agreement without cause and for its convenience at any time upon thirty (30) days written notice to the other Party. This Agreement and any SOW may be terminated immediately by GE Healthcare in the event that KAHER is (i) for any reason suspended or sanctioned by a licensing authority; (ii) found guilty of criminal or professional misconduct; (iii) excluded or suspended from participation in any government healthcare program; or (iv) insolvent or the subject of relief under any applicable bankruptcy laws, or in the event of an assignment or other arrangements for the benefit of the other Party's creditors.

Upon Termination or expiration of this Agreement, (i) KAHER will immediately cease all use of GE Healthcare Confidential Information, and shall deliver to GE Healthcare all items containing, embodying, relating to or comprising GE Confidential Information, (ii) GE Healthcare shall terminate KAHER's access to the Platform and KAHER shall cease to access and use in any manner the Platform from such expiry or termination date and (ii) all provisions that by their nature are intended to survive shall survive such expiration or termination.

18. General Conditions and Provisions.

17.1 Notices. All notices required under this Agreement will be sent by a nationally recognized overnight courier. Notices will be deemed given on the date delivered to the recipient (it being agreed that the sender will retain proof of delivery). Notices shall be sent as follows:

If to GE Healthcare:	**If to KAHER:**
No. 4 Kadugodi Industrial Area, Bangalore 560067, India	KLE University, JNMC Campus, Nehru Nagar, Belgavi 590010, Karnataka, India
Attention: Navita Chaubal General Counsel, GEHC - South Asia	**Attention:** Dr. V.D. Patil MD, DCH Registrar, KLE University

17.2 Assignment. KAHER shall not sell, assign, delegate, or otherwise transfer any of its rights or obligations hereunder without the prior written consent of GE Healthcare, and any attempt to do so in contravention of the foregoing is hereby deemed null, void and with no effect. Subject to these restrictions, this Agreement shall be binding upon and inure to the benefit of the Parties, their respective successors and assigns.

17.3 Modification and Waiver. This Agreement may not be modified and none of its terms may be waived, except by a written document signed by authorized representatives of both Parties. A waiver by a Party of any default shall not be deemed a waiver of a prior or subsequent default of the same or other provisions of this Agreement. The failure of a Party to enforce, or the delay by a Party in enforcing, any of its rights shall not be deemed a continuing waiver or a modification of this Agreement.

17.4 Disclaimer and Limitation of Liability. EXCEPT FOR DAMAGES FROM A PARTY'S WILLFUL MISCONDUCT OR A BREACH OF SECTIONS 3.a, 8, 9, 12 AND 14, EACH PARTY'S MAXIMUM AGGREGATE LIABILITY TO THE OTHER (WHETHER IN CONTRACT, TORT OR ANY OTHER FORM OF LIABILITY) FOR DAMAGES OR LOSS, HOWSOEVER ARISING OR CAUSED, WHETHER OR NOT ARISING FROM A PARTY'S NEGLIGENCE, SHALL IN NO EVENT BE GREATER THAN AMOUNTS PAID BY GE HEALTHCARE TO KAHER IN THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRECEDING THE EVENT GIVING RISE TO SUCH CLAIM. THIS LIMITATION APPLIES TO ALL CAUSES OF ACTIONS IN THE AGGREGATE. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY SPECIAL, EXEMPLARY, INCIDENTAL, INDIRECT, PUNITIVE, OR

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CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, REVENUE, AND BUSINESS), WHETHER BASED ON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), STATUTE, EQUITY, PRODUCT LIABILITY, FUNDAMENTAL BREACH, OR OTHERWISE ARISING FROM OR RELATED TO THIS AGREEMENT, REGARDLESS OF WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH DAMAGES.

17.5 Severability. If any part of this Agreement is declared invalid or unenforceable by a court of competent jurisdiction, it shall not affect the validity or enforceability of the remainder of this Agreement, unless the Agreement so construed fails to meet the essential business purposes of the Parties as manifested herein.

17.6 Relationship. It is expressly agreed that the Parties intend by this Agreement to establish between themselves the relationship of independent contractors. It is further agreed that a Party has no authority to create or assume in the other Party's name, or on behalf of the other Party, any obligation (express or implied), or to act or purport to act as agent or representative on behalf of the other Party for any purpose whatsoever. Neither GE Healthcare nor KAHER is the employer, employee, agent, partner, or co-venturer of or with the other, each being independent.

17.7 Advertising/Publications. Neither Party shall use the other Party's name, logos, trademarks, or other identifying characteristics (or that of any of its subsidiaries or Affiliates) in any marketing, training, public relations or similar publications without such Party's prior written approval.

17.8 Governing Law and Dispute Resolution. This Agreement shall be governed by and interpreted, construed, and enforced in accordance with laws of India and will be subject to jurisdiction of Courts at Bangalore, India. Any dispute, controversy, or claim relating to this Agreement (a "Dispute") will be resolved first through arbitration. Such arbitration shall be governed by the provisions of the Arbitration and Conciliation Act of 1996 or modification to it for the time being in force. The venue of arbitration shall be Bangalore, India and the cost of arbitrations will be shared by both the Parties in equal proportion unless otherwise decided by the arbitration panel. Either Party shall be entitled to apply to the competent courts at Bangalore, India for interim or interlocutory relief in respect of such arbitration. When any Dispute is under arbitration, except for the matters under Dispute the Parties shall continue to exercise their remaining respective rights and fulfil their remaining respective obligations under the Agreements during the pendency of the arbitration proceedings.

17.9 Entire Agreement. This Agreement, including all Exhibits, is intended by the Parties as a final and complete expression of their agreement on the subject hereof, and supersedes any and all prior and contemporaneous agreements and understandings. No other agreements, oral or otherwise, on the subject matter hereof shall be deemed to exist or to bind any of the Parties.

17.10 References to Parties. All references to GE Healthcare will include GE Affiliates. All references to KAHER include KAHER's employees, representatives, agents, and sub-contractors.

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers or representatives.

(Clinical Development Collaborator)	**GE Healthcare, a division of General Electric Company**
By: _____	By: _____
Authorized Signature	Authorized Signature
_____	_____
Print Name	Print Name
_____	_____
Title	Title
_____	_____
Date	Date

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Appendix A

Sites/Facilities Covered by Agreement

Site/Facility Name	Address
KAHER	JNMC Campus, Nehru Nagar, Belgaum, Karnataka 590010

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EXHIBIT A

STATEMENT OF WORK (SOW)

(Template to be used for additional SOW to be executed between GE & KAHER during the term of this agreement)

GE Healthcare ("GE Healthcare") and XXXXX ("Clinical Development Collaborator" or "CD Collaborator"), are entering into this Statement of Work ("SOW"), effective as of the date of the last signature below ("Effective Date"), pursuant to that certain Clinical Development and Feedback Agreement (the "Agreement") dated _____, between GE and Clinical Development Collaborator. This SOW is governed by the terms and conditions of the Agreement and such Agreement are incorporated herein by reference and made a part hereof. To the extent of any conflict between an SOW and the Agreement, the terms of the Agreement shall prevail and supersede. This SOW is intended to define, among other things, the scope of work under which the CD Collaborator will provide from time to time consultative, collaborative, or product design or development resources in connection with a particular GE project for a specified duration.

I. **Objective.**

GEHC is developing Artificial Intelligence algorithms for --------. The Clinical Development Collaborator is a member of GE's elite group of artificial intelligence collaborators. This consortium of hospital networks will be some of the world's first clinical practices to contribute to the creation, testing, and implementation of transformational innovation within the radiology field, aimed at improving the quality and efficiency of patient care through emerging deep learning algorithms.

Clinical development partners are needed for the following stages of the product development process:

- Stage 1: Discovery/Observational Research of Clinical Workflow and User Needs
- Stage 2: Data Curation/Annotation
- Stage 3: Data Collection for Algorithm Testing &/or Improvements
- Stage 4: Product Design Feedback
- Stage 5: Clinical Evaluation

This SOW is focused on **Stages ----**.

GE Project Manager:	**Collaborator Project Manager:** tbd

II. **General Provisions.**

The following describes in general terms the parties' respective responsibilities.

CD Collaborator Responsibilities:	1. Assign qualified employees to participate as defined in the Project Specific Provisions referenced in **Section III.** 2. Provide a single point of contact for all matters relating to this engagement. 3. Ensure that the CD Collaborator-assigned resources have sufficient time allotted to participation in the collaboration to ensure completion of assigned tasks. 4. Provide necessary facilities, equipment and telecommunications infrastructure to allow remote participation in conference calls, webinars

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	and other meetings. 5. Enable the resource(s) to travel as reasonably necessary to support the applicable project (at CD Collaborator's expense). 6. For projects involving distributed group teleconferences, provide a facilitator for each team location at which a session is scheduled who organizes the local event, handles meeting logistics (i.e., facilities, equipment, and the like), and chairs the local session. 7. For projects involving CD Collaborator production of development artifacts, adhere to GE product development and quality control standards. 8. --------
GE Responsibilities:	1. Provide a single point of contact for this engagement. 2. Organize the collaborative project, and mediate overall relationships with other organizations involved with the project. 3. Review and approve CD Collaborator's proposed personnel for the project. 4. Provide access to documents and systems required for effective participation by CD Collaborator's personnel in the work of the project, subject to CD Collaborator's and its assigned personnel's compliance with the applicable confidentiality and data privacy and security, intellectual property protection, and other relevant terms of the Agreement. 5. Monitor team dynamics to assure that the CD Collaborator personnel are effectively engaged in the project and take corrective action as needed. 6. Provide regular progress reports to the primary CD Collaborator contact regarding the work of this team. 7. Provide orientation for the CD Collaborator personnel with respect to the development project. 8. For projects involving CD Collaborator production of development artifacts provide GE product development and quality control standards. 9. ----------

III. **Project-Specific Provisions.**

A. Project Overview:

CD Collaborator will perform Image Curation/Annotation, Data Collection, Product Design Feedback for ----- artificial intelligence algorithms as set forth below.

B. Collaboration Work Product and Project Deliverables:

1. Image Curation/Annotation

2. Data Collection

GE Healthcare reserves the right to cancel subsequent data collection milestones, if the business deems they no longer have the data needs. Any data shared with GE Healthcare will be data collected in the

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normal course of business using the usual standard of care; no data will be collected solely for the purposes of the Agreement with GE Healthcare.

The intent of data collection for this project phase, is to (1) test the algorithm(s) performance on a new / separate data set and (2) if needed, leverage the additional data for more algorithm training.

CD Collaborator agrees to provide support to GE Healthcare in regulatory submissions of the algorithms produced from the data collection, by providing system information or patient demographic data needed to justify product claims, for example the age/gender demographics for image data used for algorithm validation.

Exams shall have distribution from these categories:

- -----
- -----

The following approach will be taken to identify and collect the data:

- CD Collaborator and GE will work jointly to properly identify and collect the dataset needed to support this SOW, such process may include searching reports database for key terms, processing reports with natural language processing tools, querying PACs for a desired set of accession numbers.
- CD Collaborator to review and de-identify the data and review for compliance with applicable laws. GE may assist CD Collaborator in setting up de-identification process, but CD Collaborator to remain responsible for overall process.
- All data received will be tracked by GE Healthcare by maintaining a record of the following: source of data, type of image, modality type, volume of date, date when data is received, and date of de-identification confirmation from hospital. This process will be followed in order to distinguish one batch of data from subsequent batches.

3. Product Design Feedback

Throughout the collaboration, access to interview the following personas about product feedback, will be included :

- Radilogists/Radiographers
- Clinicians

GE will be respectful and conscious about the clinical staff's time, and have reasonable requests for feedback, ultimately to ensure that the project will be of value add to end users of the product.

C. Project Schedule:

Mo. #	Ideal Month	Targeted Progress
0		
1		
2		

D. List of Key Personnel being assigned by CD Collaborator:

Role	Description	Name
Project manager	Managing the project operationally	TBD
IT manager	Extracting, de-identifying, & transferring of data to GE's.	TBD
Radiologist(s)	Annotate images, clinical consulting to GE product team	TBD

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E. Work Location(s):
All work will occur at CD Collaborator facilities at CD Collaborator's sole expense.

F. Compensation: Dollar amounts are in American dollars.

G. Payment Milestones: Dollar amounts are in US dollars.

H. SOW Term:
---- months from the last signature date.

IN WITNESS WHEREOF, the parties hereto have executed this Statement of Work to be effective as of the Effective Date.

GE HEALTHCARE	CLINICAL DEVELOPMENT COLLABORATOR
By: _____	By: _____
Print name: _____	Print name: _____
Title: _____	Title: _____
Address: _____	Address: _____
Date: _____	Date: _____

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EXHIBIT B

Terms of Use

Acceptance of the Terms of Use

The following terms and conditions, together with any documents expressly incorporated by reference (collectively, the "Terms of Use"), govern your access to and use of the Platform. The Platform provides a cloud-based infrastructure of big data platform for healthcare research and enable care providers to collaborate with third parties for the purposes of healthcare research.

Please read the Terms of Use carefully before you start to use the Platform. By accessing or using the Platform, you accept and agree to be bound and abide by the Terms of Use. If you do not want to agree to the Terms of Use, you must not access or use the Platform.

Changes to the Terms of Use

GE Healthcare may revise and update the Terms of Use from time to time at its sole discretion. All changes are effective immediately when we post them and apply to all access to and use of the Platform thereafter. Your continued use of the Platform following the posting of revised Terms of Use means that you accept and agree to the changes.

GE Healthcare reserves the right to withdraw or amend the Platform in our sole discretion without notice. We will not be liable if for any reason all or any part of the Platform is unavailable at any time or for any period. From time to time, we may restrict access to some parts of the Platform to users for maintenance or any other reason.

Accessing and Using the Service

To access and use the Platform, you will be required to register and establish your user account. You will be asked to provide certain registration details or other information. If permitted pursuant to a separate Agreement with GE Healthcare and subject to the terms of such Agreement, you may also invite others to register and establish a user account as a "Member" of your "Partner Network." It is a condition of your access and use of the Platform that all the information you provide for user registration and account set-up is correct, current and complete. You agree that all information you provide to register yourself or a Member of your Partner Network with the Platform is governed by the GE Privacy Policy (http://www.ge.com/privacy), and you consent to all actions we take with respect to your information consistent with the GE Privacy Policy. You and other authorized end-users who have registered and established user accounts for the Platform and have accepted the Terms of Use are collectively referred to as "Users".

If you have obtained a user name, password or any other piece of information as part of our security procedures, you must treat such information as confidential, and you must not disclose it to any other person or entity. You also acknowledge that your account is personal to you and agree not to provide any other person with access to this Platform or portions of it using your user name, password or other security information. You are responsible for all uses of and access to the Platform under your user name and password. You agree to notify us immediately of any unauthorized access to or use of your user name or password or any other breach of security. You also agree to ensure that you exit from your account at the end of each session. You should use particular caution when accessing your account from a public or shared computer so that others are not able to view or record your password or other personal information.

GE Healthcare has the right to disable any user name, password or other identifier, whether chosen by you or provided by us, at any time in our sole discretion if, in our opinion, you have violated any provision of the Terms of Use or the Agreement. GE Healthcare may also deny account sign-up based on your location or other reasons. You must not attempt to work around any such limitations in the Service.

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Content Rights

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In the event that you acquire any right in the foregoing Intellectual Property, you hereby assign to GE Healthcare all rights in and to the Intellectual Property, as well as any suggestions or feedback you provide in connection with the Intellectual Property; you agree to provide reasonable assistance to GE Healthcare in enforcing its rights to the Intellectual property.

GEHC does not claim ownership of the content you provide and upload on the Platform. Your content remains your content. GEHC also does not control, verify, or endorse the content that you and others make available on the Platform. Save and except the rights granted to GE Healthcare to use the Data under the Agreement, you control who may access your content, along with other Members of your Partner Network. If you share content in your records, then you agree that anyone you have shared content with may use or access that content and are otherwise authorized by applicable law to do so. You also understand and acknowledge that you are solely responsible for any content that you transmit or upload, including its legality, reliability, accuracy and appropriateness and for obtaining any necessary patient consents and authorizations. When you give others access to your content on the Platform, they may use, reproduce, download, distribute, display, transfer, transmit, and communicate to the public the content. If you do not want others to have that ability, do not use the Platform to share your content.

If you share content on the Platform in a way that infringes others' rights, including intellectual property rights or privacy rights, you are breaching the Terms of Use. You represent and warrant that you have all the rights and authorizations necessary for you to grant the rights in this section and the use of the content does not violate any law. GE Healthcare may remove your content from the Platform at any time if you breach the Terms of Use.

No Medical Responsibility

GE Healthcare does not warrant the accuracy, completeness or usefulness of the information uploaded on the Platform by the Users. Any reliance you place on such information is strictly at your own risk. We disclaim all liability and responsibility arising from any reliance placed on such materials by you or any User of the Platform, or by anyone who may be informed of any of its contents. Furthermore, the Platform contains decision support or other tools that may be used by qualified healthcare providers only. These tools do not make clinical decisions or replace the medical judgment of properly trained healthcare providers. It remains the healthcare provider's responsibility to exercise its independent medical judgment in providing care based on all relevant information and factors.

The Platform is not intended to function as a primary document retention or storage tool. Data that you upload or create in the Platform are stored only for a limited period of time and that such data will be automatically deleted from the Service without notice to Users. You are responsible for backing up the data that you store on the Platform. In the absence of other contractual obligations, if access to the Platform is canceled, we may permanently delete your data from our servers, and we have no obligation to return data to you after the access to the Platform is canceled. If data is stored with an expiration date, we may also delete the data as of that date. Deleted data may be irretrievable.

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The Platform is intended to be used only for healthcare research and You undertake to use the Platform only for the purpose of healthcare research. You agree not to use the Platform for any clinical services in any manner.

Trademarks

Trademarks, logos and service marks displayed on the Platform are registered and unregistered trademarks of General Electric Company, its licensors or content providers, or other third parties. All of these trademarks, logos and service marks are the property of their respective owners. Nothing on the Platform shall be construed as granting, by implication, estoppel, or otherwise, any license or right to use any trademark, logo or service mark displayed on the Platform without the owner's prior written permission, except as otherwise described herein. We reserve all rights not expressly granted in and to the Platform and its content. The Platform and all of its content, including but not limited to text, design, graphics, interfaces and code, and the selection and arrangement thereof, is protected as a compilation under the copyright laws of the United States and other countries. All other third-party names, logos, product and service names, designs and slogans on the Platform are the trademarks of their respective owners.

Prohibited Uses

You may use the Platform only for lawful purposes and in accordance with the Terms of Use and this Agreement. The Platform also may contain features where you may transmit direct messages or post and share comments with other Users of the Platform. You agree not to use the Platform:

- In any way that violates any applicable federal, state, local or international law or regulation (Including, without limitation, any laws regarding personal data privacy and security).
- Infringe any patent, trademark, trade secret, copyright or other intellectual property or other rights of any other person.
- Transmit or upload any content which is defamatory, obscene, indecent, abusive, offensive, harassing, violent, hateful, inflammatory or otherwise objectionable.
- Promote sexually explicit or pornographic material, violence, or discrimination based on race, sex, religion, nationality, disability, sexual orientation or age.
- For the purpose of exploiting, harming or attempting to exploit or harm minors in any way by exposing them to inappropriate content, asking for personally identifiable information or otherwise.
- To transmit, or procure the sending of, any advertising or promotional material, including any "junk mail", "chain letter" or "spam" or any other similar solicitation.
- To impersonate or attempt to impersonate GE Healthcare, a GE Healthcare employee, another User or any other person or entity (including, without limitation, by using e-mail addresses or registration names associated with any of the foregoing).
- To engage in any other conduct that restricts or inhibits anyone's use or access of the Platform, or which, as determined by GE Healthcare, may harm GE Healthcare or Users of the Platform or expose them to liability.
- Promote any illegal activity, or advocate, promote or assist any unlawful act.
- Additionally, you agree not to:
- Use the Platform in any manner that could disable, overburden, damage, or impair the Platform or interfere with any other party's use of the Platform, including their ability to engage in real time activities through the Platform.
- Use any robot, spider or other automatic device, process or means to access the Platform for any purpose, including monitoring or copying any of the material on the Platform.
- Use any manual process to monitor or copy any of the material on the Platform or for any other unauthorized purpose without our prior written consent.
- Use any device, software or routine that interferes with the proper working of the Platform.
- Introduce any viruses, trojan horses, worms, logic bombs or other material which is malicious or technologically harmful.

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- Attempt to gain unauthorized access to, interfere with, damage or disrupt any parts of the Platform, the server on which the Platform is stored, or any server, computer or database connected to the Platform.
- Attack the Platform via a denial-of-service attack or a distributed denial-of-service attack.
- Otherwise attempt to interfere with the proper working of the Platform.

Monitoring and Enforcement; Termination

We have the right to:

- Take appropriate legal action, including without limitation, referral to law enforcement, for any illegal or unauthorized use of the Platform.
- Terminate or suspend your access to all or part of the Platform for any or no reason, including without limitation, any violation of the Terms of Use and this Agreement.

Without limiting the foregoing, we have the right to fully cooperate with any law enforcement authorities or court order requesting or directing us to disclose the identity or other information of anyone posting any materials on or through the Platform. YOU WAIVE AND HOLD HARMLESS GEHC AND ITS AFFILIATES, LICENSEES AND SERVICE PROVIDERS FROM ANY CLAIMS RESULTING FROM ANY ACTION TAKEN BY GE HEALTHCARE AND ANY OF THE FOREGOING PARTIES DURING OR AS A RESULT OF ITS INVESTIGATIONS AND FROM ANY ACTIONS TAKEN AS A CONSEQUENCE OF INVESTIGATIONS BY EITHER GE HEALTHCARE OR SUCH PARTIES OR LAW ENFORCEMENT AUTHORITIES.

However, GE Healthcare does not undertake to review material before it is uploaded on the Platform, and cannot ensure prompt removal of objectionable material after it has been uploaded. Accordingly, GE Healthcare assumes no liability for any action or inaction regarding transmissions, communications or content provided by any User or third party. GE Healthcare has no liability or responsibility to anyone for performance or nonperformance of the activities described in this section.

Data Privacy

You explicitly consent to the use of the protected health information (PHI) and other personally identifiable information (PII) you provide via the Platform, including storing, processing, and disclosing the data in accordance with this Terms of Use and the Agreement. You confirm that you have the legal authority to authorize GE Healthcare and its subcontractors to process all PHI and PII you provide via the Platform and that you have obtained the authorization or consent (as required by applicable law) of all persons whose PHI and PII you provide.

GE Healthcare considers your use of the Platform to be private. However, GE Healthcare may access, disclose, or preserve information associated with your use of the Platform, including (without limitation) your personal information and content, or information that GE Healthcare acquires about you through your use of the Platform (including IP address and third-party information) when GE Healthcare forms a good-faith belief that doing so is necessary; (a) to comply with applicable law or to respond to legal process from competent authorities; or (b) to enforce this Terms of Use and the Agreement or protect the rights or property of GE Healthcare or our customers.

GE Healthcare retains the right to block or otherwise prevent delivery of any type of email or other communication to or from the Platform as part of our efforts to protect the Platform, protect our customers, or stop you from breaching this Terms of Use and the Agreement. The technology or other means we use may hinder or prevent your use of the Platform.

In order to provide you access to the Platform, we may access, collect, maintain, analyze, prepare derivatives from and otherwise use certain information about Platform performance, your machine and your Platform use. We may automatically acquire this information from your machine.

Geographic Restrictions

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GE Healthcare provides the Platform only for use or access by and data transmissions to persons located in India. We recognize that it is possible for you to obtain access to the Platform from any jurisdiction in the world, but we have no practical ability to prevent such access. The Platform has been designed to comply with the laws of India. If any material on the Platform is contrary to the laws of the place where you are when you access it, the Platform is not intended for you, and we ask you not to use the Platform. You are responsible for informing yourself of the laws of your jurisdiction and complying with them.

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You understand that we cannot and do not guarantee or warrant that data uploaded to the Platform by the Users will be free of viruses or other destructive code. You are responsible for implementing sufficient procedures and checkpoints to satisfy your particular requirements for anti-virus protection and accuracy of data input and output, and for maintaining a means external to our site for the storage, retention, and restoration of any data, in original, copy or back-up form. GE HEALTHCARE WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGE CAUSED BY A DISTRIBUTED DENIAL-OF-SERVICE ATTACK, VIRUSES OR OTHER TECHNOLOGICALLY HARMFUL MATERIAL THAT MAY INFECT YOUR COMPUTER EQUIPMENT, COMPUTER PROGRAMS, DATA OR OTHER PROPRIETARY MATERIAL DUE TO YOUR USE OF THE PLATFORM OR ANY DATA OR ITEMS OBTAINED THROUGH THE PLATFORM.

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NO ADVICE OR INFORMATION, WHETHER ORAL OR WRITTEN, OBTAINED BY YOU FROM GE HEALTHCARE OR THROUGH THE PLATFORM SHALL CREATE ANY WARRANTY NOT EXPRESSLY STATED IN WRITING. TO THE EXTENT THAT STATE STATUTES OR OTHER REGULATIONS EXPRESSLY FORBID THE LIMITATION OR EXCLUSION OF CERTAIN WARRANTIES OR CONDITIONS, THE ABOVE EXCLUSIONS WILL NOT APPLY TO YOU ONLY TO THE EXTENT CONTRARY TO SUCH EXPRESS STATE LAW.

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Limitation on Liability

YOU ACKNOWLEDGE AND AGREE THAT UNDER NO CIRCUMSTANCES, INCLUDING, WITHOUT LIMITATION, NEGLIGENCE, SHALL GE HEALTHCARE OR ITS PARENTS, SUBSIDIARIES, AFFILIATES, OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, OR SUPPLIERS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING FROM OR IN CONNECTION WITH THE USE OF OR THE INABILITY TO USE THE PLATFORM OR ANY CONTENT CONTAINED ON THE PLATFORM, OR RESULTING FROM UNAUTHORIZED ACCESS TO OR ALTERATION OF YOUR TRANSMISSIONS OR DATA, OR OTHER INFORMATION THAT IS SENT OR RECEIVED OR NOT SENT OR RECEIVED, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS, USE, DATA OR OTHER INTANGIBLES, EVEN IF GE HEALTHCARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

YOU ACKNOWLEDGE AND AGREE THAT THIS IS A REASONABLE ALLOCATION OF RISK. TO THE EXTENT THAT A STATE STATUTE OR OTHER REGULATION DOES NOT ALLOW THE LIMITATION OR EXCLUSION OF LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OR OTHER DAMAGES EXCLUDED HEREIN, THE ABOVE EXCLUSIONS WILL NOT APPLY TO YOU ONLY TO THE EXTENT CONTRARY TO SUCH EXPRESS STATE LAW.

Indemnification

You agree to indemnify, defend and hold harmless GE Healthcare and its Affiliates and their officers, directors, employees, contractors, agents, licensors, service providers, subcontractors and suppliers from and against any and all losses, liabilities, expenses, damages and costs, including reasonable attorneys' fees and court costs, arising or resulting from your use of the Platform and any violation of these Terms of Use and the Agreement, including, without limitation, intellectual property infringement and privacy violations. If you cause a technical disruption of the Platform or the systems transmitting the Platform to you or others, you agree to be responsible for any and all losses, liabilities, expenses, damages and costs, including reasonable attorneys' fees and court costs, arising or resulting from that disruption. GE Healthcare reserves the right, at its own expense, to assume exclusive defense and control of any matter otherwise subject to indemnification by you and, in such case, you agree to cooperate with GE Healthcare in the defense of such matter.

Limitation on Time to File Claims

TO THE EXTENT PERMITTED BY LAW, ANY CAUSE OF ACTION OR CLAIM YOU MAY HAVE ARISING OUT OF OR RELATING TO THE TERMS OF USE OR THE PLATFORM MUST BE COMMENCED WITHIN ONE (1) YEAR AFTER THE CAUSE OF ACTION ACCRUES, OTHERWISE, SUCH CAUSE OF ACTION OR CLAIM IS PERMANENTLY BARRED.

Waiver and Severability

No waiver by GE Healthcare of any term or condition set forth in the Terms of Use shall be deemed a further or continuing waiver of such term or condition or a waiver of any other term or condition, and any failure by GE Healthcare to assert a right or provision under the Terms of Use shall not constitute a waiver of such right or provision.

If any provision of the Terms of Use is held by a court or other tribunal of competent jurisdiction to be invalid, illegal or unenforceable for any reason, such provision shall be eliminated or limited to the minimum extent such that the remaining provisions of the Terms of Use will continue in full force and effect.

Assignment

GE Healthcare may assign, transfer, or otherwise dispose our rights and obligations under this Terms of Use, in whole or in part, at any time without notice. You may not assign this contract or transfer any rights to use the Platform.

No third-party beneficiaries

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Platform Software

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We may automatically check your version of the software. We may also automatically download to your computer upgrades to the software to update, enhance, and further develop the Platform.

Any software we provide is licensed, not sold. Unless we notify you otherwise, the software license ends when your access to the Platform ends. You must then uninstall the software, or we may disable it. You must not work around any technical limitations in the software. You must not disassemble, decompile, or reverse engineer any software that's included in the Platform, except and only to the extent that the applicable copyright law expressly permits doing so.

The software is subject to applicable U.S. export laws and regulations and other applicable export laws and regulations. You must comply with all domestic and international export laws and regulations that apply to the software. These laws include restrictions on destinations, end users, and end use.

Your Comments and Concerns

For any concerns, contact your site administrator for any support or question. We may send you, in electronic form, information about the Platform, additional information, and information the law requires us to provide. You consent to GE Healthcare providing you required information by e-mail at the e-mail address you specified when you signed up for access to the Platform or by access to a GE Healthcare web site that we identify. Notices emailed to you will be deemed given and received when the email is sent. If you don't consent to receive notices electronically, you must stop using the Platform.

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EXHIBIT C

BUDGET

Details of Overall Budget

Sr No		Cost in USD (For Data per annum in INR)
1	Clinical Costs (Consent, Scan & Acquisition, Filing)	1827000
2	Deidentification and Minimal Annotation cost (Technologist & Radiologist effort cost)	1820000
3	Reports (Radiology & Pathology) / Management Fee	1692320
4	GST & Taxes @18%	960820
	Total	**6300000**

- Storage, Network & Transfer Costs of Data to GE / YOY : INR 1750000
- Research Infrastructure & Data cataloging, indexing (GPU, CPU) costs to GE YOY : INR 1750000
- Partnerships is Data and Research partnerships with GE, with GE contributing data infrastructure (storage, compute) with estimates indicated above. This will enable GE's Projects, Partner's Project and Joint Projects to be executed. The infrastructure that GE will deploy to extract Data will be GE managed and will be returned to GE at the end of agreement. The projects will be focusing on but not limited to care areas which are of mutual interest to both parties :
  - o Cardiology
  - o Oncology
  - o Radiology
- Assumptions :
  - o Quarterly Payment Schedule, for three years subject to completion of Deliverables every quarter
  - o First Payment is GATED by Infrastructure readiness.
  - o Payment is not GATED by amount or quality of data generated in a quarter

Total : 1 Cr (in Cash, in kind) for 4 quarter

Payment Schedule:

Milestone #	Deliverable Description	Payment in INR (Including GST 18%)	Estimated Invoice Timeline
1	(a) Patient Consent Infrastructure (registered patients) for research and development, scientific, education, marketing and regulatory purposes developed by management team. (b) IT Assessments for data (Images, Imaging Reports, Lab Reports) collection completed (c) Data centralization infrastructure deployed, and consented patient data centralized. Sort out patient-id duplication issues and data management issues with 3rd party outsourced vendors. (d) Cloud Access Infrastructure setup for joint use and continuous consented data being collected	3150000	Q3 – Q4 2019

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	(e) Subsequent payments including GST@18%: INR 1575000	1575000	Q1 2020 Q2 2020
Q2	Data & Reports (De-identified Images; Reports) for consented patients (or with EC approval)	6300000	Q3-2020 TO Q2-2021
3	Data & Reports (De-identified Images; Reports) for consented patients (or with EC approval)	6300000	Q3-2021 TO Q2-2022

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Attachment A

This Attachment governs to the extent that a Supplier Processes GE Data, including Personal Data, and/or has access to a GE Information System in connection with the Agreement (as defined below). In the event of any inconsistency or conflict between a provision of this Attachment and a provision of the Agreement with respect to a subject covered by this Attachment, the provision requiring higher protection for GE Data shall prevail. The requirements in this Attachment are in addition to any confidentiality obligations between GE and Supplier under the Agreement.

Part A: Definitions

(i) *Agreement* as used in this Attachment, means the relevant contract, agreement, statement of work, task order or purchase order governing the provision of services and/or deliverables by Supplier to GE. For clarity, this Attachment is a part of the Agreement.

(ii) *GE* means the General Electric Company, a General Electric Company operating unit, or a General Electric Company affiliate signing the Agreement with Supplier.

(iii) *GE Data* is any GE or its affiliate's Confidential Information, as defined in the Agreement, that is Processed in connection with performance of the Agreement.

(iv) *GE Information System(s)* means any networks, systems and/or computers managed by GE, which includes laptops and network devices.

(v) *Mobile Devices* means tablets and smartphones running mobile operating systems (e.g., iOS, Blackberry OS, Android, or Windows Mobile operating systems). Laptops are not considered to be Mobile Devices.

(vi) *Personal Data* is a category of GE Data that includes any information that relates to an identified or identifiable natural person (Data Subject), as such relation is defined under applicable law or regulation. Legal entities are Data Subjects where required by law.

(vii) *Process or Processing* means to perform any operation or set of operations upon GE Data, whether or not by automatic means, including but not limited to collecting, recording, organizing, storing, adapting or altering, retrieving, accessing, consulting, using, disclosing by transmission, disseminating, or otherwise making available, aligning or combining, blocking, erasing, or destroying.

(viii) *Security Incident* is any actual or suspected event in which GE Data is or may have been lost, stolen, improperly altered or destroyed, used for a purpose not permitted under the Agreement, or accessed by any person other than Supplier Personnel pursuant to the Agreement.

(ix) *Security Notices* are any written communications, notices, filings, press releases, or reports related to any Security Incident.

(xii) *Supplier* is the entity that is a party to the Agreement.

(xiii) *Supplier Information System(s)* means any Supplier systems and/or computers used to Process GE Data pursuant to the Agreement, which includes laptops and network devices.

(xiv) *Supplier Personnel* means Supplier's employees, as well as its permitted affiliates, suppliers, subcontractors, and agents and their respective employees.

Part B: Collecting, Processing and Sharing GE Data

Supplier shall implement appropriate organizational, technical, GE Data; and unlawful Processing of GE Data. Supplier is responsible for compliance with all terms of the Agreement (including this Attachment) by Supplier Personnel and for following GE's instructions concerning the Processing of GE Data.

Organizational security controls shall include the following at a minimum:

1. Supplier and Supplier Personnel shall Process GE Data, and access and use GE Information Systems, only on a need-to-know basis and only to the extent necessary to perform services under the Agreement or as otherwise instructed by GE in writing.

2. Prior to providing access to any GE Data to any Supplier Personnel, Supplier must obligate them to comply with the level of security required in the Agreement, including this Attachment. Supplier shall take reasonable steps to ensure continuing compliance by such Supplier Personnel and will remain responsible at all times for their compliance.

3. Supplier must maintain information security policies and procedures consistent with the requirements of this Attachment.

4. Supplier Personnel with access to GE Data must participate in appropriate information security training prior to obtaining access to GE Data and periodically thereafter.

5. Supplier must ensure each account through which GE Data may be accessed is attributable to a single individual with a unique ID (not shared) and each account must require authentication (e.g., password) prior to accessing GE Data.

6. Supplier shall undertake reasonable measures to terminate physical and logical access to GE Data by Supplier Personnel no later than the date of separation or transfer to a role no longer requiring access to GE Data; where such Supplier Personnel have been assigned GE SSO credentials, Supplier must notify GE of any such separation or transfer no later than the day of that event.

7. GE Data shall not be Processed on personal accounts (e.g., individual email or cloud services accounts such as Gmail, Yahoo, Dropbox, or Google Drive) or on personally-owned computers, devices or media.

8. Unless prohibited by applicable law or regulation, Supplier will notify GE promptly and act only upon GE's instruction concerning any request by a third party, including without limitation law enforcement, governmental authority, or in connection with litigation or other court process for disclosure of GE Data or for information concerning the Processing of GE Data in connection with the Agreement, as well as any request received from an individual to access or request modification of his/her Personal Data.

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and physical measures and controls to protect and ensure the security and confidentiality of GE Data; to prevent accidental, unauthorized or unlawful destruction, alteration, unauthorized disclosure or access, modification or loss of GE Data; misuse of passwords. User account credentials (e.g., login ID, password) must not be shared.

10. Supplier must implement and maintain controls to detect and prevent unauthorized access, intrusions and computer viruses and other malware. At a minimum such controls must include network layer security devices (e.g. firewalls and intrusion detection/prevention systems), client and server-side antivirus programs that include up-to-date antivirus definitions, and installation into production of all critical patches or security updates as soon as possible, but not later than thirty (30) days from the release of any such updates or patches.

11. Supplier must maintain documented change management procedures that provide a consistent approach for controlling, implementing and documenting changes (including emergency changes) for Supplier Information Systems that includes appropriate segregation of duties.

12. Unless otherwise expressly agreed in the Agreement, development and testing environments must be physically and/or logically separated from production environments and must not contain GE Data unless specified in the Agreement.

13. Supplier must maintain reasonable back-up and disaster recovery processes and procedures. Any back-up media containing GE Data stored at Supplier's site must be kept in a secure location (e.g., locked office or locked file cabinet) and be encrypted to a standard consistent with industry practice. If off-site media storage is used, Supplier must have a media check-in/check-out process with locked storage for transportation. Back-up information must be given the same level of physical and environmental protection as the level of control applied at the main site.

14. Workstations must not be left authenticated when unattended and must be password or PIN protected when not in use. An inactivity lock must be implemented on workstations.

15. Network layer security devices must allow only authorized connections.

16. Mobile Devices used to Process GE Data (including emails) must have strong mobile device security controls including passcode, minimum passcode length, inactivity lock, and a process to immediately remotely wipe lost or stolen devices.

Physical security controls shall include the following at a minimum on all Supplier facilities where GE Data may be Processed:

17. Physically secure perimeters and external entry points must be suitably protected against unauthorized access (e.g. barriers such as walls, card controlled entry gates). Access to all locations must be limited to Supplier Personnel and authorized visitors only. Reception areas must be manned or have other means to control physical access.

18. Visitors must be required to sign a visitor register and be escorted or observed at all times while on the premises.

19. A clear desk policy must be enforced throughout the Supplier facilities. Documents that contain GE Data must be kept secured (e.g. locked office or file cabinet) when not in use.

Technical security controls on Supplier Information Systems shall include the following at a minimum:

9. Supplier must use strong passwords consistent with technology industry practices, including minimum password length, lockout, expiration period, complexity, encryption, changing of default passwords, and usage of temporary

incident, whether discovered by Supplier, GE, or a third party, which shall include providing GE a detailed description of the Security Incident, the type of data that was the subject of the Security Incident, the identity of each affected person, and any other information GE reasonably may request concerning such affected persons and/or the details of the Security Incident, as soon as such information can be collected or otherwise becomes available. Supplier shall designate an individual responsible for management of the Security Incident, and will identify such individual to GE promptly. Supplier shall maintain a log of such Security Incidents and review the log periodically for improvements in Supplier's security policies and practices.

2. Other than approved Security Notices, or to law enforcement or as otherwise required by law or regulation, Supplier will not make or permit any public statements concerning GE's involvement with any Security Incident to any third-party without the explicit written authorization of GE's Legal Department.

3. Supplier shall pay for or reimburse GE or the applicable GE affiliate for all costs, losses and expenses relating to any Security Incident experienced by Supplier, including without limitation, costs of forensic assessments, Security Notices, credit monitoring and fraud alert services, and all other remedies required by applicable law and regulation or required under GE's contractual commitments.

Part D: Audits

1. Supplier will monitor the effectiveness of its security program, including security controls on Supplier Information Systems, no less frequently than every twelve (12) months. Upon request, Supplier shall provide to GE written reports of any such assessments, which GE will treat as confidential. Supplier must use all reasonable efforts to remediate within thirty (30) days any items rated as high or critical (or similar rating indicating similar risk).

2. GE reserves the right to conduct an audit upon thirty (30) days prior written notice, including but not limited to: (i) a review of Supplier's applicable policies, processes, and procedures, (ii) a review of the results of Supplier's most recent vulnerability assessment (e.g., application vulnerability scanning, penetration testing, and similar testing results) and accompanying remediation plans, and (iii) on-site assessments of Supplier's physical security arrangements and Supplier Information Systems. Any such audit will take place during Supplier's regular working hours and will not unreasonably interfere with Supplier's operations; any audit of Supplier Information Systems will take place pursuant to pursuant to a mutually agreeable audit plan. Supplier agrees to cooperate fully with GE or its designee during such audits and to provide access to facilities, appropriate resources, applicable supporting documentation, and complete security assessment questionnaires as may be requested. Supplier shall not be required to divulge any information relating to its other customers to GE in a manner that may put Supplier in breach of its obligations of confidentiality to such customers or any other legal requirements.

3. Subject to the confidentiality provisions of the Agreement, GE

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Part C: Security Incidents

1. Supplier shall notify GE within a reasonable period, in no event to exceed seventy-two (72) hours after discovery, or shorter if required by applicable law or regulation, of any Security Incident experienced by Supplier involving any GE Data. Supplier shall report any Security Incidents to GE's Cyber Incident Response Team at gecirt@ge.com or 1-800-4GE-CIRT, or at such contact information communicated to Supplier from time to time. Supplier shall reasonably cooperate with GE in its investigation of an

regulatory requirements, Supplier agrees to cooperate with GE to comply with such requirements. Such cooperation may include, without limitation:

1. Execution of additional agreements required by applicable law or regulation (e.g., EU Standard Contractual Clauses).

2. Implementation of additional security controls required by applicable law (e.g. U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA), US Sarbanes-Oxley Act, U.S. Gramm-Leach-Bliley Financial Services Modernization Act (GLBA) Section 501(b) Standards for Securing Customer Information).

3. Completion of regulatory filings applicable to Supplier (e.g. EU data protection authority filings).

4. Completion of required regulatory audits (e.g., U.S. Food and Drug Administration (FDA), central banks such as the U.S. Federal Reserve).

Part F: Personal Data

1. Supplier shall comply with all applicable laws and regulations applicable to Supplier's activities concerning Personal Data governed by this Attachment, including those concerning notice and consent, onward transfer to a third party and international transfer, and will act only on GE's written instruction concerning any such transfers. Supplier must receive approval from GE prior to (i) moving Personal Data from its GE-approved hosting jurisdiction to a different hosting jurisdiction; or (ii) provisioning remote access to such Personal Data from any location other than the hosting jurisdiction or other GE-approved jurisdiction.

2. Any computers, devices or media (e.g., laptop computers, phones/PDAs, USB drives, back-up tapes) containing Personal Data must be encrypted at rest. Encryption also must be employed when transferring Personal Data over public networks/Internet. Supplier must maintain cryptographic and hashing algorithm types, strength, and key management processes consistent with industry practices.

3. In the event Supplier Processes Personal Data that is subject to additional regulatory requirements, or in a manner subject to additional regulatory requirements, Supplier agrees to cooperate with GE to comply with such requirements. Such cooperation may include, without limitation: a) Entry into U.S. Protected Health Information Agreement, linked here [LINK], where Supplier will Process any PHI; b) where applicable, certification that the Supplier meets the requirements of the US-EU or US-Swiss Safe Harbor and is properly listed on the US Department of Commerce Safe Harbor list with respect to the data accessed and services provided under the relevant Agreements. If Supplier's Safe Harbor certification lapses for any reason during the term, Supplier shall promptly notify GE and shall timely agree with GE upon alternative means of satisfying the associated legal requirements concerning adequacy of international data transfers.

or its representative may review, audit, monitor, intercept, access and disclose any information provided by Supplier that is Processed or stored on GE Information Systems, as well as any activity in the GE network or on GE Mobile Devices accessing the GE network.

Part E: Regulatory Requirements

In the event Supplier Processes GE Data that is subject to additional regulatory requirements, or in a manner subject to additional

Part G: Termination

1. Supplier shall, within 30 (thirty) days of termination of the Agreement or if requested during the term of the Agreement, cease all Processing of GE Data and return to GE all copies of GE Data. In lieu of returning copies, GE may at its sole discretion, require Supplier to destroy all copies of GE Data, using agreed upon methods to ensure such GE Data is not recoverable, and certify to such destruction.

2. Supplier may continue to retain GE Data beyond the period prescribed in Part G.1 where requested by GE in writing and the parties agree, or as part of its standard back-up procedures and/or to the extent required to comply with applicable law or regulation, provided that (i) Supplier notifies GE prior to the Agreement's termination or expiration of the obligation, including the specific reasons for such retention; (ii) Supplier has a documented retention period and secure deletion procedure for such copies, with back-up copies retained no longer than 6 (six) months from the date on which they were captured, and legally required copies retained only to the end of their legally required retention period; (iii) following such period, all copies and back-up copies are deleted in such a manner that they are not recoverable; (iv) Supplier performs no Processing of GE Data other than that necessitated by retaining or deleting the relevant copies; and (v) Supplier continues to comply with all the requirements of this Attachment in relation to any such retained GE Data until the same is securely deleted.

3. Termination or expiration of the Agreement, for any reason, shall not relieve the Supplier from its obligation to continue to protect GE Data to which it has access in accordance with the terms of the Agreement and this Attachment.

Part H: Miscellaneous

GE or its Affiliate may require Supplier to provide certain personal information such as the name, address, telephone number, and e-mail address of Supplier's representatives in transactions to facilitate the performance of the Agreement. GE, its Affiliates, and its contractors may store such data in databases located and accessible globally by their personnel and use it for necessary purposes in connection with the performance of the Agreement, including but not limited to Supplier payment administration. GE or the applicable GE affiliate will be the Controller of this data for legal purposes, and agrees to use reasonable technical and organizational measures to ensure that such information is processed in conformity with applicable data protection laws. Supplier may obtain a copy of the Supplier personal information by written request, or submit updates and corrections by written notice to GE.

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4. Certain GE businesses (including but not limited to GE Healthcare) and business processes are certified to the US-EU and US-Swiss Safe Harbor Frameworks (Safe Harbor). As Safe Harbor-certified entities, the relevant GE businesses are obligated to require Supplier to provide at least the same level of privacy protection for Personal Data as is required by the relevant Safe Harbor principles. Supplier understands and agrees that this Attachment is designed and intended to satisfy this requirement of the Safe Harbor and that it shall comply with this Attachment in its entirety to satisfy such compliance requirements.

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MEMORANDUM OF UNDERSTANDING

BETWEEN

Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA),
Bengaluru, India
and
KLE Academy of Higher Education and Research (KAHER),
Belgaum, India

FOR COOPERATION IN THE FIELD OF RESEARCH & EDUCATION

PREAMBLE

Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA), located at Bangalore, India is a Deemed University recognized by the Ministry of Human Resource Development, Govt. of India. It offers Bachelors, Masters, Post-graduate programs, and Doctoral Programs in the field of Yoga. The S-VYASA University is a pioneer in the field of Yoga Research and Education.

KLE Academy of Higher Education and Research (KAHER), located in Belgaum, India is a Deemed University recognized by the Ministry of Human Resource Development, Govt. of India. The institution offers programs for Under-graduate and Post-graduate students and Doctoral scholars in the fields of Medicine, Dental, Pharmacy, Physiotherapy, Ayurveda, and Nursing. The institution also includes the KLE hospital which is the epicenter for research and hands-on training for the Graduate students.

SCOPE OF AGREEMENT

This MoU is signed between Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA), and KLE Academy of Higher Education and Research (KAHER), for the purpose of Research and Education in the field of Yoga.

Objectives of MoU

- Both the parties mutually intend to conduct high quality research projects and publish in high impact journals
- To combine the best of the technology with the best of the traditional wisdom to innovate new tools for health and wellness
- To conduct and support joint workshops and seminars to disseminate usefulness of Technology in Traditional medicine

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Areas of Cooperation

- Collaborative research projects on Yoga
- Developing health screening tools, particularly tools which may use alternative medicine diagnostic methods
- Participating in community health projects (including health camps disease screening, field runs and health education) together with various NGO / partners
- Developing wearable sensors / measurement tools to assess Yoga and Meditation
- Using technology and innovations in the field of Indian traditional medicine
- Conducting workshops and seminars related to the topic of technology and alternative medicine
- Faculty exchange programs, to the extent possible within existing programs at each institution

Terms of Agreement

This memorandum is effective immediately upon its signature by the parties. Progress in achieving the objectives referred to herein will be reviewed periodically as mutually agreed and the memorandum may be amended at any time by mutual consent. Both parties reserve the right to terminate this memorandum by either party with one month written notice given to the other party.

Confidentiality

Neither party shall, at any time disclose to any third party any confidential information of the other party which is acquired in the course of activities under this Memorandum, a collaborative project, without the prior written consent of the other party. The confidential obligations herein will not apply to information in the public domain; information in the possession of the receiving party prior to the disclosure of the information; information which is independently developed by the receiving party; information required to be released by law; or information which is rightfully received by the receiving party from third parties without any breach of confidentiality obligations.

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Intellectual Property

Joint Inventions: Inventions made jointly by employees and/or students of S-VYASA with employees and/or students of KAHER, and make use of data produced from the collaborative work, shall be jointly owned by S-VYASA and KAHER. S-VYASA and KAHER also agree to notify each other after an invention disclosure is received by either organization's technology licensing office.

S-VYASA Inventions: Title to any invention conceived or first reduced to practice solely by employees of S-VYASA apart from the collaborative work, or prior to the start of the collaborative work, shall remain with S-VYASA.

KAHER Inventions: Title to any invention conceived or first reduced to practice solely by employees of KAHER apart from the collaborative work, or prior to the start of the collaborative work, shall remain with KAHER.

Patent Filing: KAHER shall have the first right to file a patent application on any joint inventions (at KAHER's expense) which shall include as named inventors the appropriate employees and/or students from KAHER and S-VYASA. The KAHER Technology Licensing Office shall decide whether or not KAHER shall proceed with patent filing. If the KAHER Technology Licensing Office decides not to proceed with a patent filing, then S-VYASA and the inventors shall jointly decide how to proceed with any patent filings at their own expense. The licensing of any issued patent and the distribution of royalties to the inventors shall follow the standard KAHER policy. KAHER and S-VYASA shall jointly discuss filing additional patents in India and/or other countries.

For patents filed by KAHER under this MoU, S-VYASA will have the right to mention its co-authorship in its presentations and marketing material. KAHER will have right to mention its co-authorship in its presentations and marketing material for patents filed by S-VYASA under this MoU.

Ethics Approvals

It is the responsibility of the investigators from each site to obtain necessary approvals for conducting this study and to ensure compliance with national and global guidelines on biomedical ethics. Each investigator is responsible for any litigation that arises from data collection at their site.

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Publications

Parties agree that any publication or conference presentation that makes use of the results and data produced from the collaborative work between KAHER and S-VYASA shall be mutually approved by both parties, and the principal investigators from both parties shall be invited to be co-authors of the publication or presentation. Each investigator has the right to decline the invitation to be a co-author. Both parties acknowledge that it may be necessary to delay publication in order to identify patentable subject matter and allow time for patents to be filed.

Validity and Termination

- Memorandum will enter in to force on the date of signing
- Memorandum is valid for the period of five years
- Parties may terminate this MoU at any time by written notice to the other party not later than one month.

Signatures

S-VYASA	KAHER
Date :- **Dr. H R Nagendra** Chancellor, S-VYASA Bengaluru, India	Date :- **Prof. (Dr.) Vivek A Saoji** Vice Chancellor, KAHER Belgaum, India
Witnesses:	
Dr. Manjunath N K Director – R & D S-VYASA, Bengaluru, India	

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA27982406745947S
Certificate Issued Date	:	12-Mar-2020 12:26 PM
Account Reference	:	SHCIL (FI)/ ka-shcil/ SHCIL BELGAUM/ KA-BL
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Purchased by	:	SUCHIRAYU HEALTHCARE SOLUTIONS LIMITED
Description of Document	:	Article 12 Bond
Description	:	MEMORANDUM OF UNDERSTANDING
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	SUCHIRAYU HEALTHCARE SOLUTIONS LIMITED
Second Party	:	KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH BGM
Stamp Duty Paid By	:	SUCHIRAYU HEALTHCARE SOLUTIONS LIMITED
Stamp Duty Amount(Rs.)	:	2,000 (Two Thousand only)

STOCK HOLDING BELAGAVI

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This MEMORANDUM OF UNDERSTANDING ("MOU") is entered into on this the **16th** day of **March, Two Thousand Twenty (EFFECTIVE DATE)** at **Hubballi**

HUBLI-30.

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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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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

BETWEEN

Suchirayu Healthcare Solutions Limited
No. 29/8/9/10, Javali Garden, Off Gokul Road,
Hubballi-580030
Represented by its Managing Director
Dr Rajendra Dugani

(HEREINAFTER called as **SUCHIRAYU** which expression shall mean and include its Board of members, representatives, successors in office, official executors etc.) **ON ONE PART**

AND.

KLE Academy of Higher Education & Research
J.N.M.C Campus, Nehru Nagar, Belagavi.
Represented by its Registrar
Prof Dr. V. A Kothiwale

(HEREINAFTER called as **KAHER** which expression shall mean and include his administrators, successors in office, executors etc.) **ON THE OTHER PART.**

THAT SUCHIRAYU is the absolute owner of Scheduled premises named as Suchirayu Hospital (hereinafter referred to as "Scheduled Premises") situated at Sy No. 29/8/9/10, Javali Garden, Hubballi. Suchirayu Healthcare Solutions Limited is a company registered under the Companies Act, 1956. The company is the absolute owner and administrator of a 300 bedded Multi Speciality hospital consisting of 22 departments.

WHEREIN KAHER is a deemed to be University established U/s 3 of the UGC Act 1956 having its registered office at JNMC Campus, Belagavi. It has 9 constituent units affiliated to it. KAHER is desirous of establishing a Medical college of 150 intake, hence the KLE Society, which is the

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sponsoring society of KAHER has purchased a land at Sy Nos 141, 142 and 145 of Gabbur village Hubbali, approximately measuring 29 acres for the proposed college and teaching hospital.

WHEREIN KAHER is willing to obtain on lease the SUCHIRAYU Hospital academically as a teaching hospital for the proposed medical college at Hubballi. Suchirayu Hospital is situate at a minimum distance of 3 Kms from the proposed college. Hence it has approached SUCHIRAYU to lease out the scheduled premises and SUCHIRAYU has agreed for the same. A Lease agreement dated 16.03.2020 has been executed between the parties.

WHEREIN the Schedule Property is more fully described at Annexure 'A' attached hereunder.

NOW THIS AGREEMENT WITNESSETH AND THE PARTIES AGREE AS FOLLOWS-

RELATIONSHIP OF THE PARTIES

1) **THAT** KAHER SHALL take the hospital premises academically and shall run the hospital in the name of KLE-SUCHIRAYU Hospital. The said hospital shall be the Teaching Hospital for the proposed Medical College of KAHER.

2) **THAT** the administration of the Scheduled premises shall be the sole responsibility of SUCHIRAYU. KAHER shall not interfere in matters of administration, operation and finance. KAHER shall not be responsible for any financial liabilities of SUCHIRAYU.

3) **THAT** the scheduled premise is a furnished 250 bedded Multi Speciality hospital. It consists of various/different departments which are required for a teaching hospital as per MCI norms. The details of departments and other facilities available at SUCHIRAYU, are shown at 'Annexure B'.

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4) **THAT** SUCHIRAYU has entered into a Medical Services Agreement dated: 10th July, 2016, effective from 01st August 2017 with HealthCare Global Enterprises Limited, having its registered office at HCG Towers, No.8, P. Kalinga Rao Road, Sampangi Ramanagar, Bangalore 560 027 for running, operating and managing SUCHIRAYU on an exclusive basis ("Medical Services Agreement"). Parties agree that the Medical Services Agreement shall continue to be valid and enforceable and nothing contained in the MOU shall affect the rights of HealthCare Global Enterprises Limited under the Medical Services Agreement.

TERM AND TERMINATION

This MOU shall be in effect initially for a period of 03 years commencing from 15.03.2020 and concluded on 14.03.2023. The period may be further extended for a period of 1 year, by mutual consent. Either party may terminate the MOU by written notice sent to the authorised officer of the institution by a prior notice of 3 months. This MOU shall not be terminated on any grounds other than for the breach of any of the conditions enumerated in this agreement.

FINANCIAL CONSIDERATION

1. **THAT** the consideration fixed under the MOU is Rs. 2 crores per year (referred to as the Clinical levy fee) KAHER shall pay GST on above said amount to SUCHIRAYU. While realising the lease amount, TDS shall be deducted by KAHER as per IT Rules and certificate 16A will be issued by KAHER. Standard deductions such as TDS will be deducted as per Income Tax Act.

2. **THAT** KAHER shall pay the clinical levy fee by way of cheque or DD drawn in favour of SUCHIRAYU. The same shall be paid in the following manner

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- Rs. 2 crores shall be paid on the date of signing of this MOU (which is non-refundable)
- Rs. 2 crores shall be paid after obtaining permission from MCI for the proposed college or 13th month from the Effective Date (Whichever is earlier).
- Rs. 2 crores shall be paid on or before 5th day of the 25th month from the Effective Date.

DUTIES & LIABILITIES OF KAHER

1. **THAT** the necessary changes in nomenclature such as board, hoardings, bills, invoices etc shall be changed as per the new name. The expenses incurred shall be borne by KAHER.

2. **THAT** KAHER is at liberty to make any minor construction, renovation or infrastructural changes as per the requirement prescribed by the Medical Council of India, at its own cost by obtaining prior consent from SUCHIRAYU.

3. **THAT** KAHER may avail the services of doctors, nursing staff and other clerical and non-technical staff in the scheduled premises for necessary MCI approval. In case KAHER makes additional recruitment then the salary and other benefits shall be paid by KAHER. Their services are governed by KAHER service rules.

4. **THAT** KAHER is not responsible for any civil or criminal liability arising out of the scheduled premises. However any liability arising out of the misconduct of KAHER or its employees, KAHER shall be responsible.

5. **IT IS AGREED THAT** if KAHER avails any of the services from SUCHIRAYU at any point of time during MCI inspection, then KAHER shall make payment for such services eg. ward charges, nursing charges, doctor's charges, dietician charges etc.,.

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6. **THAT** SUCHIRAYU has provision for department of ophthalmology, however necessary equipment shall be installed by KAHER at its own cost.

7. **FURTHER** KAHER shall set up 50 beds in different wards at its own cost and shall make provision for additional increase phase-wise as per requirement.

8. **KAHER** shall be at liberty to conduct various health programmes, conferences, seminars such as World Cancer Day, World Diabetes Day etc at its own cost. SUCHIRAYU shall provide space to conduct such functions, without any additional costs. All other expenses for promotion and operation of such programmes shall be borne by KAHER.

9. **FINALLY AGREED THAT** On termination of the agreement KAHER shall pull down the infrastructure put on by it and take back the movable assets. KAHER SHALL hand over the property as it was at the time of letting out..

DUTIES & LIABILITIES OF SUCHIRAYU

1. **THAT** SUCHIRAYU has entered into agreement for outsourcing of cafeteria and housekeeping services. These agreements shall not affect the MOU. They are not binding on KAHER and continue to remain in force.

2. **WHEREAS** the SCHEDULE PREMISES consists of a Pharmacy run by SUCHIRAYU. The licence renewal charges, taxes if any shall be paid by SUCHIRAYU.

3. **THAT** SUCHIRAYU shall allow the students, staff and authorised representatives of KAHER to visit the scheduled premises at all reasonable times.

KLE Academy of Higher Education and Research * Deemed-to-be University BELAGAVI

ATTESTED

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

4. **THAT** the aspects of insurance, warranty, guarantee and replacement of any machinery, equipment etc., shall be the sole responsibility of SUCHIRAYU. However in case of upgradation of any equipment or machinery, for MCI purpose shall be done by KAHER at its own cost. Any additional equipment or resources procured by KAHER for any purpose shall be maintained and insured by KAHER. All revenue generated by upgradation of technology or Resources will be billed and earned by Suchirayu only. No share of revenue will be shared by KAHER.

LAW AND ARBITRATION

The provisions of this MOU shall be governed by and construed in accordance with Indian Law. Any dispute, controversy or claims arising out of or in relation to this MOU shall be settled by arbitration in accordance with the provisions of the Arbitration and Conciliation Act. 1996. The arbitrary tribunal shall be composed of one arbitrator to be mutually appointed by the parties. The place of arbitration shall be at Hubballi. The award of the arbitrator shall be final and binding upon the parties. The cost of arbitration shall be borne by the Parties on equal sharing basis. The Courts at Dharwad shall be the Jurisdictional Courts

NAME & LOGO

THAT neither of the parties shall use the name and logo of the other party for any promotional, commercial, banking or any other purposes of whatsoever nature. Neither party shall take undue advantage or make any profit from the use of name and Logo of the other party.

BINDING NATURE OF MOU

Notwithstanding anything contained in this MOU the parties shall be bound by the provisions of this MOU. In case any inconsistencies/difficulties arise in any agreements connected to this MOU, then the provisions of this MOU shall prevail over such inconsistencies/difficulties (verbal/oral).

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
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and Research, BELAGAVI

ANNEXURE – 'A'

SCHEDULE OF THE PROPERTY

All that Piece and Parcel of hospital property bearing Nos. (i) 29/8 measuring 11 Guntas 11 annas, (ii) Sy No. 29/9 measuring 11 guntas 11 annas and (iii) Sy No. 29/10 measuring 11 guntas 10 annas, all the properties totally admeasuring 3540/95 square meters situated at Javali Garden, Off Gokul Road, Hubballi included within the Hubli Dharwad Municipal Corporation. The property consists of 7 floors (G+5-2) including 22 departments, Pharmacy, cafeteria and open space for garden and parking. The property is bounded as under

North	:	R.S. No. 3
South	:	Road
East	:	Part of Sy. No. 2
West	:	Part of Sy No. 6, 7

ANNEXURE – 'B'

INFRASTRUCTURAL FACILITIES

The SUCHIRAYU hospital consists of 22 departments, 1 Pharmacy, 1 cafeteria and other recreations facilities. It consists of the following

Sl.No	Infrastructural Facilities	
1	Departments	22
2	OT (equipped & unequipped) ICU	4 major OTs (3+1CTVS) 2 Minor OTs 6
3	Radiology	1
4	Laboratory consisting of pathology, biochemistry and microbiology	1
5	Blood Bank	1
6.	250 beds divided as under beds with surgical specialities beds with Medical specialities beds with OBG facilities beds with clinical facilities.	 100 100 20 30
Note: The hospital has feasibility of being periodically upgraded.		

ATTESTED

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

IN WITNESSTH, WHEREOF the parties have put their hands and have affixed their signature of this Memorandum of Understanding on the day, month and year first above mentioned.

FOR AND ON BEHALF OF
SUCHIRAYU HEALTH CARE SOLUTIONS LIMITED

SIGNATURE

Name: Shri Rajendra Duggani

Designation: Managing Director, SUCHIRAYU

Place: Hubballi

Date: 16.03.2020

FOR AND ON BEHALF OF
KLE ACADEMY OF HIGHER EDUCATION & RESEARCH

SIGNATURE

Name: Prof Dr V. A Kothiwale

Designation: Registrar, KLE Academy of Higher Education & Research

Place: Hubballi

Date: 16.03.2020

Witness.

1. (Dr Arvind G. Kadadi)

2. Dr Suresh Korlhalli

(Dr. M. G. Hiremath)

ATTESTED

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