



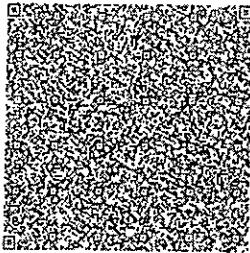
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ATTESTED

Dr. V.A.Kothiwale
Registrar

CLINICAL STUDY AGREEMENT – "Maternal DHA supplementation and offspring neurodevelopment in India (DHANI-2)"
KLE Academy of Higher Education and Research
Belagavi-590 010, Karnataka

This Clinical Study Agreement (hereinafter the "Agreement") is entered into and effective this 27th November, 2015 ("Execution Date") between

Public Health Foundation of India, is a registered society under the Indian Societies Registration Act, 1860. Having its registered office at ISID Campus, Institutional Area, Vasant Kunj, New Delhi – 110070 (hereinafter "PHFI")

Statutory Alert:

The authenticity of this Stamp Certificate should be verified at "www.shoilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.

For PHFI
In case of any discrepancy please inform the Competent Authority.

For KLEU/JNMC



-and-

«K.L.E. University's Jawaharlal Nehru Medical college (JNMC) » with its principal place of business at «K.L.E. University's Jawaharlal Nehru Medical college (JNMC), »Nehru Nagar, Belgaum»- 590010», «Karnataka», «India» (hereinafter the "Institution")

PHFI and The Institution, are hereinafter individually referred to as the "Party" or collectively referred to as the "Parties".

WHEREAS, PHFI is coordinating and is the main representative of an investigator-initiated study i.e., "Maternal DHA supplementation and offspring neurodevelopment in India (DHANI-2)" (hereinafter the "Study"), at the study site i.e. Prabhakar Kore Hospital(PKH), KLE University, Jawaharlal Nehru Medical College, Belgaum, Karnataka (hereinafter the "Study Site") the protocol (hereinafter the "Protocol", which term shall include any amendments made to the Protocol from time to time) which has been developed by the Public Health Foundation of India").

AND WHEREAS Wellcome Trust DBT/India Alliance' (hereinafter **DBT / the Sponsor**) has given a Grant to PHFI vide Grant No. IA/CPHE/14/1/501/498 as the Research Coordinating Centre (here in after the "RCC") which is responsible to carry out certain activities such as regulatory approval, assistance to the centre for ethics committee approval, and monitoring;

AND WHEREAS, PHFI may also conduct sub studies (hereinafter the "**Substudy (ies)**") in conjunction with the Study, and all references to the Study shall include any Sub study(ies) that are conducted and the references to the Protocol shall include any protocols related to such Sub study(ies);

AND WHEREAS, the continuance in force of this Agreement is to be contingent of the continuance of the provision of funding and other support for the Sponsor;

AND WHEREAS, in order generally to meet international regulatory and other standards and requirements relative to the design and conduct of clinical trials of the type like the Study, and to better ensure the robustness and broader applicability of the results of the Study, it is necessary for JNMC (Institution) to carry out the Study in collaboration with PHFI and the recruiting centre that is located at the Institution;

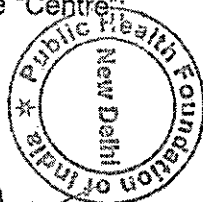
AND WHEREAS, Dr. Shweta Khandelwal is the "PRINCIPAL INVESTIGATOR" and representative of PHFI, shall retain supervisory responsibility for this study. Any change in the scope of work requires written approval from Dr. Shweta Khandelwal. The scientific and technical direction of JNMC's portion of the research study, as set forth in the statement of work (see Appendix A, attached), shall be under the direction of Dr. M.K. Swamy, HOD OBGYN ("Study Site Collaborator").

AND WHEREAS Centre for Chronic Disease Control' (hereinafter the "**CCDC**") will be an observatory partner.

AND WHEREAS the Study Site Collaborator i.e. and Institution possess the resources and expertise to carry out a portion of the Study and wish to assist PHFI by acting as a recruiting centre for the Study;

AND WHEREAS the Study Site Collaborator and Institution are hereinafter referred to jointly and severally as the "Centre".

For PHFI



[Handwritten signature]

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



NOW THEREFORE, the undersigned Parties have agreed upon the rights and obligations set forth below, which shall apply between them in connection with the performance of the Study.

ARTICLE-1: PERFORMANCE OF THE STUDY

- 1.1 The Institution and the Study Site Collaborator shall carry out the Study in strict conformance with: generally accepted standards of good clinical practice, including the Guidance for Good Clinical Practice of the International Conference on Harmonization (hereinafter the "ICH-GCP"); Revised Schedule Y of the Indian Drugs and Cosmetic Rules (hereinafter Sch Y), ; the Protocol; this Agreement; the written instructions of RCC (PHFI); all other applicable Study documents approved by the governing institutional review board or research ethics board (hereinafter the "IRB"); all applicable procedures, rules, regulations and guidelines established by, or otherwise applicable within the Institution governing the performance of studies involving human subjects at the Institution; all applicable rules, orders, regulations and guidelines (hereinafter the "Regulatory Authority"); all applicable Laws
- 1.2 The Institution and the Study Site Collaborator hereby represents and agrees that: a) they have, and at all times during the course of the Study will have, personnel with appropriate training, information, licenses, approvals, and certifications necessary to safely, adequately and lawfully perform the Study in accordance with Good Clinical Practice; b) that the Study Site Collaborator is currently and will throughout the performance of the study be authorized to perform his/her duties under this Agreement; and c) the Study Site Collaborator has received, read and understood the Protocol, a confirmation of which is attached hereto as Exhibit A.
- 1.3 The Study Site Collaborator shall obtain written approval by the IRB for the Protocol and for the informed consent form to be used (hereinafter the "Consent Form") prior to initiation of the Study and during the conduct of the Study if required and shall immediately provide copies of all such documentation to PHFI. The Study Site Collaborator shall be provided a sample Consent Form from PHFI. The Investigator/Collaborator may add additional information if required by their IRB, however, such changes should not be material and should, without limitation, not change Sponsor intent concerning the minimum level of information provided to each human subject (hereinafter the "Subject") in order to obtain Subject's consent, nor modify the compensation provision without PHFI's consent.
- 1.4 The Study Site Collaborator shall obtain a written consent from each Subject participating in the Study as specified in the Protocol and as required by Applicable Laws prior to enrolling such Subject into the Study and shall further assure that all such Subjects understand the Consent Form approved by the ethics committee. The Investigator/Collaborator shall maintain the Consent Form in the Subject's permanent record.
- 1.5 It is anticipated that 1500 Subjects will be recruited into the Study. The Site Investigator/Collaborator shall start recruiting Subjects only after he/she has received written authorization from PHFI/RCC to start recruitment, such authorization to be provided after receipt of all relevant documentation at PHFI/RCC. PHFI reserves the right to limit the recruitment of further Subjects or cease the recruitment at the Centre. Upon receipt of written notice from PHFI to cease recruitment, the Study Site Collaborator shall immediately cease further recruitment of Subjects.
- 1.6 The Institution and the Study Site Collaborator represent and agree that they are not presently and shall not at anytime during the performance of the Study, be under any

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For PHFI _____



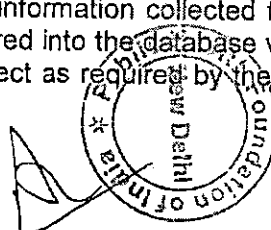
obligation to a third party, or be subject to any other legal impediments, which would conflict with their duties hereunder, or that might otherwise impair the acceptance by a regulatory body of the data collected by the Centre.

- 1.7 The Institution and the Study Site Collaborator agrees to provide to PHFI/RCC, any documentation required by Regulatory Authorities and/or Applicable Laws including but not limited to the Study Site Collaborator's *curriculum vitae*, each signed by the Study Site Collaborator, or any other documentation or information that relates to disclosure of the financial interests of the Study Site Collaborator in the Study. The Institution represents that: a) the Study Site Collaborator has not been debarred pursuant to any Applicable Laws or by any regulatory authority (all references to regulatory authority within this **Agreement shall include** Regulatory Authority); and b) that the Institution or the Study Site Collaborator have not been disqualified from participating in clinical trials by any regulatory authority. Additionally, the Institution agrees not to use any person for the services provided hereunder (i) that has been debarred, disqualified or is under investigation by the FDA/MHRA/DCGI for debarment action or disqualification; or (ii) that has been found by any regulatory authority to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations (all of the forgoing in items (i) and (ii) hereinafter "Disqualified"). Furthermore, the Institution agrees that they shall promptly notify PHFI in the event of such debarment, conviction, threat, disqualification or indictment of the Study Site Collaborator or any person that has provided services under this Agreement, during the term of this Agreement or three (3) years following its expiration or earlier termination. The Study Site Collaborator may appoint other individuals deemed appropriate as sub site investigators (hereinafter the "Sub Site investigators") to assist in the conduct of the Study in accordance with the Protocol, provided that the Study Site Collaborator shall be required to act in accordance with proper professional judgment in making all such appointments. The Study Site Collaborator shall be responsible for leading the team of Sub Site investigators, who in all respects shall be bound by the same obligations as the Study Site Collaborator, and the Study Site Collaborator shall inform and keep informed in detail all Sub Site Investigators about all such obligations as they may exist from time to time. Further, the Study Site Collaborator shall be responsible for ensuring that all staff and personnel within the Institution who participate in the Study have read and understood the Protocol.

The Study Site Collaborator shall immediately inform the RCC of any serious unexpected suspected adverse reactions (hereinafter "SUSAR"), as defined in the Protocol. The Site Investigator/Collaborator shall promptly report adverse events (hereinafter "AE") to PHFI in accordance with the procedures outlined in the Protocol. The Institution and the Study Site Collaborator shall comply with all the requirements Sch Y in terms of safety reporting including notifying the relevant authority in writing of any SUSAR as defined in the Protocol. During the course of the Study, should the Institution and/or Investigator receive any correspondence from the regulatory authorities or the IRB in relation to the Study or the Study Drug, the recipient(s) shall immediately provide to PHFI a copy of any such correspondence.

- 1.8 The Institution and/or the Study Site Collaborator shall prepare and maintain complete, accurately written records, accounts, medical notes, reports, and data including all supportive documentation for each Subject (hereinafter the "Source Documents") in accordance to the operating procedures required by PHFI/RCC and all Applicable Laws. The Institution and/or the Study Site Collaborator shall ensure that information collected for the trial is recorded on the appropriate worksheet and entered into the database via the corresponding Case Report Forms (CRFs) for each Subject as required by the Protocol. Completed hard copies of these CRFs shall be

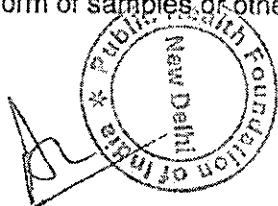
For PHFI




sent in batches to the PHFI, New Delhi every six months. Any personnel from the Coordinating Centre visiting the site can also carry the forms with him/her and hand over duly to the PI, PHFI, New Delhi.

- 1.9 The Institution and/or the Study Site Collaborator shall maintain a copy of all documents, including the Source Documents, relating to this Study for the longer of: a) fifteen (15) years after the Study is completed or discontinued by PHFI or b) as required by the Applicable Laws.
- 1.10 The Institution and the Study Site Collaborator shall cooperate and permit, upon request, PHFI, and/or Sponsor or RCC, and/or officials of any regulatory authority to examine and inspect the Institution's facilities and equipment required for performance of the Study and inspect and copy all data, reports, work products and results relating to the Study. PHFI's/ RCC's access to records for monitoring or audit does not entitle them to copy any Subject's personal health information. If the Institution or the Study Site Collaborator is notified of an inspection by a regulatory authority, the entity so notified shall immediately inform PHFI about the pending inspection and authorize PHFI, or any person designated by them, to participate in this inspection. The Institution and/or the Study Site Collaborator shall immediately communicate to PHFI the information that arises from such inspections by the regulatory authorities. It is expressly agreed that PHFI shall not compensate the Institution or the Study Site /Collaborator for any audits and/or inspections and that the assistance and availability of the Institution and the Study Site Collaborator for the audits and inspections is included in the amount mentioned in Article 4.
- 1.11 Should the Study Site Collaborator leave the Institution or otherwise become unavailable during the term of this Agreement, the Institution and PHFI shall make reasonable efforts to find a replacement Study Site Collaborator of similar qualifications who is acceptable to both the Institution and PHFI. The Institution shall ensure that any replacement agrees to be bound by all the terms and conditions hereunder and, where required by PHFI, a new agreement will be executed between the Institution, the replacement Study Site Collaborator and PHFI, or between the replacement Study Site Collaborator and PHFI only, at the option of PHFI. Notwithstanding the foregoing, PHFI, in its sole and absolute discretion, may elect not to approve person proposed as a replacement Study Site Collaborator, in which event PHFI shall have the right to terminate the Study in accordance with Section 9.1.
- 1.12 PHFI/RCC or its representative shall provide free of charge, to the Study Site Collaborator, a sufficient amount of the Study Drugs to conduct the Study. PHFI/RCC shall provide the Study Drugs only after receipt of copies of the IRB approval and all other documents required by RCC/PHFI prior to initiation of recruitment at the Centre. The Institution and the Study Site Collaborator shall use only the Study Drugs provided through RCC and shall use the Study Drugs solely for the purposes of conducting the Study and shall ensure that the Study Drugs are stored in accordance with the instructions provided by RCC. The Institution and/or the Site Study Collaborator shall ensure that an accurate record of the quantity of Study Drugs received and dispensed to each Study Subject is maintained. The Institution and/or the Study Site Collaborator shall promptly provide to RCC all required documentation with respect to the usage and the disposal of the Study Drugs. After completion of the Study, the Institution and/or the Study Site Collaborator shall dispose of the Study Drugs in accordance with the instructions from PHFI/RCC or its representative. For further certainty, the Institution and the Study Site Collaborator shall not use for the Study any drugs that they may receive in the form of samples or otherwise from sources than PHFI.

For PHFI



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Dr. V.A. Kothiwale
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KLE Academy of Higher Education and Research,
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ARTICLE- 2: PERFORMANCE PERIOD

This Agreement shall be valid for a period of 5 years starting with effect from 1st Dec 2015 or until the Study has been completed or upon written notice from PHFI of early termination of the Study, whichever occurs first, unless otherwise terminated earlier in accordance with Section 9.1 (hereinafter referred to as the "Effective Duration"). The duration of the Agreement may be further extended upon mutual agreement of the Parties only in case of a No-Cost Extension.

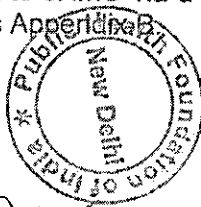
ARTICLE- 3: OWNERSHIP OF DATA, RESULTS, INVENTIONS AND PATENTS

- 3.1 PHFI/RCC (in its sole and absolute discretion) shall have all right, title and interest in and to all data and results of the Study. The Institution and the Site Investigator/Collaborator hereby specifically disclaim any right, title or interest of any kind whatsoever to the data and results of the Study or to information received by the Institution or the Study Site Collaborator as a result of or in the course of performing the Study, except to the extent that such rights are specifically granted hereunder.
- 3.2 In the event that any discovery or invention is made by the Institution, the Study Site Collaborator, any Sub Site investigators or any agents or employees of the Institution or the Site Collaborator in the course of or in connection with the performance of the Study, such discovery or invention shall be communicated immediately to a PHFI/RCC representative. All right, title and interest in and to any such discovery and invention shall belong to PHFI/RCC and/or its assignee (in its sole and absolute discretion). The Institution and the Study Site Collaborator shall have no right, title or interest in or to such discovery or invention, and consequently shall refrain from, and shall cause its Sub-Site investigators and other employees or agents to refrain from filing any application on their discovery or invention with any patent or other relevant authority. If PHFI/RCC and/or its assignee desires to file patent applications on such discovery or invention, whether in its name or in the name of any designee, it will do so at its own expense, and those persons participating in the discovery or invention hereby assign all right, title and interests to such discovery or invention to PHFI/RCC (or to such third party as PHFI/RCC may instruct) without any additional compensation, and, if requested by PHFI/RCC to do so, assist in the preparation of such patent applications. PHFI/RCC shall be under no obligation to patent, develop, market or otherwise utilize the results of the work done by the Study Site Collaborator, Sub Site investigators or other agents or employees of the Institution or the Study Site Collaborator in connection with this Agreement.
- 3.3 The Site Study Collaborator and the Institution shall ensure that all employees, Sub Site investigators or other agents hired to perform services hereunder shall agree to fulfill the obligations herein, especially in relation to the assignment of rights in discoveries and inventions to PHFI/RCC as applicable.

ARTICLE- 4: COST AND PAYMENT

- 4.1 The host organization has obtained funding from the India Alliance (SPONSOR) towards implementing the early career fellowship of Shweta Khandelwal at the Public Health Foundation of India (PHFI), New Delhi. The institution, JNMC is the organization which will be involved in the subject recruitment and trial implementation. With this background a total of 50,45,600 (Fifty lakhs forty five thousand and six hundred) INR is being apportioned to JNMC via a Sub Grant Agreement attached as ~~EXHIBIT~~ ~~ANNEXURE~~ ~~APPENDIX~~ ~~ANNEXURE~~ the budget is enclosed as Appendix B.

For PHFI



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Dr. V.A.Kothiwale
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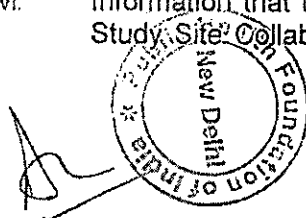
For KLEU/JNMC

- 4.2 The payment schedule is given in detail at Exhibit B of the aforementioned Sub-Grant at sub-clause 4.1.
- 4.3 The Study Site Collaborator and the Institution shall be jointly and severally responsible for the payment of any or all taxes that may apply to any payment they receive, including, without limitation, for paying any value-added tax, sales tax, or similar tax imposed by the taxation authorities in any jurisdiction.
- 4.4 The Institution and the Study Site Collaborator shall review the payment details generated by PHFI that shall accompany each payment and shall inform PHFI in writing in accordance with the instructions provided in the payment details of any discrepancies that may exist in the payment(s) received and the payment(s) expected. At the completion of the Study, the Institution and the Study Site Collaborator shall ensure that any such discrepancies that may exist, if any, are brought to the attention of PHFI no later than four (4) months after the Study database is locked. The Parties shall work diligently and in good faith to resolve any such discrepancies. Should PHFI not receive written notice of any final discrepancies within such 4 month period, then all payments required to be made hereunder shall be deemed to have been made in full, and the Institution and the Study Site Collaborator shall cease to have, and each hereby waives, all rights to receive further compensation in connection with the Study.

ARTICLE- 5: CONFIDENTIAL INFORMATION

- 5.1 The Study Site Collaborator and the Institution agrees to maintain or cause to be maintained in confidence all information received under this Agreement, and all information resulting from or related to work performed under this Agreement (hereinafter the "Confidential Information"). This obligation shall be binding for the term of this Agreement and for a period of ten (10) years after termination. Notwithstanding the foregoing, the obligation of non-disclosure and non-use shall not apply to the following:
- i. Information after such time that it is or becomes publicly available through no fault of the Institution and/or the Study Site Collaborator; or
 - ii. Information that is already independently known to the Institution and/or the Study Site Collaborator, as shown by their prior written records, provided that the Institution and/or the Study Site Collaborator so advises PHFI promptly upon the Institution's and/or the Study Site Collaborator discovery that the information is already independently known to the Institution and/or the Study Site Collaborator; or
 - iii. Information after such time that it is disclosed to the Institution and/or the Study Site Collaborator on a non-confidential basis by a third party with the legal right to do so or who is not otherwise bound by confidentiality and/or non-use obligations to PHFI; or
 - iv. Is or becomes public knowledge as required by law (subject to the requirements set forth below); or
 - v. Is disclosed with the prior written consent of PHFI or its authorized agents; or
 - vi. Information that is independently developed by the Institution and/or the Study Site Collaborator, its employees and/or agents who have not had

For PHFI



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ATTESTED
 Dr. V.A. Kothiwale
 Registrar
 KLE Academy of Higher Education and Research,
 (Deemed-to-be-University's 2019 (UGC Act, 1956))
 Belagavi-590 010, Karnataka



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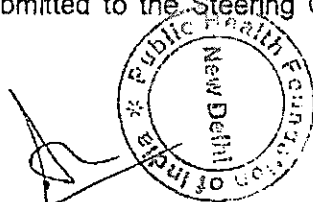
access to the Confidential Information as shown by written documentation kept in the ordinary course of business.

- 5.2 The Study Site Collaborator and the Institution shall ensure that all employees or other agents hired to perform services hereunder will be bound by the same obligations of confidentiality and nondisclosure and non-use as imposed upon the Institution and the Study Site Collaborator under the terms of this Agreement.
- 5.3 Nothing in this Agreement shall be construed to restrict the Parties from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case the Party requested to make such disclosure shall timely inform the other Parties and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, the Party required to make such disclosure shall permit and assist the other Parties in its attempt to limit such disclosure by appropriate legal means. All such information disclosed in such manner shall be treated as confidential for all other purposes.
- 5.4 In the event that PHFI shall come into contact with Subjects' medical records, PHFI shall hold in confidence the identity of the Subjects and shall comply with the ICH-GCP guidelines regarding the confidentiality of such records.
- 5.5 All Parties agree to comply with all applicable laws and regulations regarding protection of personal and/or health information.

ARTICLE- 6: PUBLICATIONS

- 6.1 The study data arising from the Study shall be the sole property of the PHFI ;
- 6.2 The study data arising from the Study, which is related to the contribution of the site, shall be licensed to the site on a perpetual, royalty-free, non-exclusive basis for non-commercial purposes including for teaching, research and publication purposes on publication of the final report;
- 6.3 Any invention or discovery arising from the study data which is related to the contribution of the site shall be the property of PHFI provided such invention or discovery is directly related to the Study.
- 6.4 As the Study is a single centre study, the Parties agree that, consistent with international standards for scientific and medical publications, the data from the centre will be analyzed and reported as such (hereinafter the "Study Results"). The Institution and the Study Site Collaborator shall not make any publications before the Study Results are published. The Steering Committee shall, regardless of the outcome, submit the initial publication to a reputable, peer reviewed, biomedical journal or otherwise make public the Study Results as soon as practicable.
- 6.5 Notwithstanding the foregoing, the Steering Committee and PHFI may at any time disclose or publish all information as they may reasonably decide where such disclosure or publication relates to the safety of the Study Subjects, patients in general, or the general public.
- 6.6 Proposals for all publications, abstracts, and other presentations arising from the Study will be submitted for approval to the Steering Committee. Each abstract must be submitted to the Steering Committee, through PHFI, for approval at least eight (8)

For PHFI _____



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Dr. V.A. Kothiwale
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Belagavi-590 010, Karnataka



weeks prior to the date it is intended to be submitted for publication. The Steering Committee or a subcommittee there of, may recommend changes prior to approval.

6.7 The Institution and the Study Site Collaborator shall not use the name(s) of PHFI or any of its employees in advertising or promotional material or publication without the prior written consent of PHFI, provided however that the Institution may acknowledge, in general terms, the existence of the Agreement and the Institution's receipt of financial support from PHFI. PHFI shall not use the name(s) of the Institution and the Study Site Collaborator in advertising or promotional material or publication (excluding Study Results) without having received the prior written consent(s) of the appropriate party.

ARTICLE- 7: RELATIONSHIP OF PARTIES

Any work performed by the Institution, the Study Site Collaborator and any agents, subcontractors or employees of the Institution and the Site Investigator/Collaborator under this Agreement shall be as independent contractors and not as partners, joint venturers, employees, subcontractors or agents of PHFI. The Institution, the Study Site Collaborator, and any agents or employees of the Institution and the Study Site Collaborator shall not have the power to bind or designate PHFI or any persons affiliated with PHFI.

ARTICLE- 8: NOTICE

Any notice required or permitted by this Agreement shall be in writing and shall be delivered to the addresses or facsimile numbers specified below (or as updated by subsequent notice) as follows, with notice deemed given as indicated: (a) by personal delivery, when delivered personally; (b) by courier, upon courier's verification of delivery; (c) by certified or registered mail, return receipt requested, upon postal service's verification of delivery; or (d) by facsimile, upon confirmed successful transmission at sender's location.

If to the Institution:

«The Registrar
KLE University's Jawaharlal Nehru Medical College (JNMC)»
«Nehru Nagar, Belgaum»
«Karnataka», «590010»
Tel: Phone.No : +918312444444
Fax No : +918312493777
If to PHFI:

Vice President Finance & Resources
Public Health Foundation of India
Plot No. 47, Sector-44
Institutional Area,
Gurgaon-122002,
Haryana, India

ARTICLE- 9: TERMINATION

9.1 This Agreement may be terminated early as follows:

- (a) PHFI may terminate this Agreement by providing written notice to the Institution and the Study Site Collaborator, which notice (hereinafter the "Termination Notice") and termination shall, ^{APPROVED} subject to the on-going obligations of each of the Parties pursuant to paragraph 9.1 (c) below, be

For PHFI



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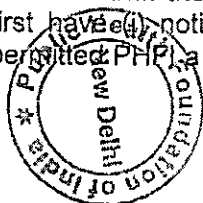
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act 1956)
Belgaum-590010, Karnataka



effective immediately upon receipt of the Termination Notice by the Institution or the Study Site Collaborator if:

- (i) Any competent regulatory authority requires that part or all of the Study be discontinued or materially altered; or
 - (iii) The Study Site Collaborator or the Institution is Disqualified (as defined in Section 1.8); or
 - (iv) Sponsor fails or ceases to provide funding for the Study, or notifies PHFI that it intends at a future date to cease such funding; or
 - (v) The Centre does not enrol at least one (1) Subject within three (3) months of receiving the relevant IRB approval to proceed with the Study; provided that PHFI shall have first provided preliminary notice to the Site Investigator/Collaborator in writing that PHFI may, in its discretion, terminate this Agreement unless the Centre enrolls at least one (1) Subject within four (4) weeks of the Site Investigator/Collaborator receipt of such preliminary notice; or
 - (vi) The Institution or the Study Site Collaborator, or any Sub Site investigator/ Collaborator or employee of the Institution or Study Site Collaborator, fails to perform or performs improperly any of its material obligations under this Agreement (hereinafter a "Centre Default"), provided that PHFI shall first have (i) notified the Institution and/or the Study Site Collaborator, as applicable, in writing of such Centre Default, and (ii) permitted the Party or Parties in Centre Default a reasonable amount of time (hereinafter the "Cure Period"), to cure the Centre Default, which Cure Period shall be stated in the notice from PHFI, but which shall in no event exceed thirty (30) days; or
 - (vii) PHFI shall have sent to the Institution and the Study Site Collaborator a preliminary notice in writing indicating PHFI's intention to terminate the Agreement (hereinafter the "Preliminary Notice"), provided that the Preliminary Notice shall have been received by the Institution and the Study Site Collaborator at least thirty (30) days prior to the date the PHFI issues its Termination Notice and further provided that both the Preliminary Notice and the Termination Notice may be issued by PHFI in its sole and absolute discretion.
- (b) The Institution and the Study Site Collaborator may terminate this Agreement by jointly providing written notice to PHFI, which notice and termination shall, subject to the ongoing obligations of each of the parties pursuant to paragraph 9.1 (c) below, be effective immediately upon receipt of written notice by PHFI if:
- i) The IRB or Regulatory Authority requires that either the Institution or the Study Site Collaborator, or both, cease a material part or all of their activities in connection with the Study; or
 - ii) If PHFI fails to perform or performs improperly any of its material obligations under this Agreement (hereinafter "PHFI Default"), provided that the Institution and/or the Study Site Collaborator shall first have (i) notified PHFI in writing of such PHFI Default, and (ii) permitted PHFI a reasonable amount of time to cure the PHFI Default,

For PHFI



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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ATTESTED



10

which Cure Period shall be stated in the notice from the Institution and/or the Study Site Collaborator, but which shall in no event exceed thirty (30) days.

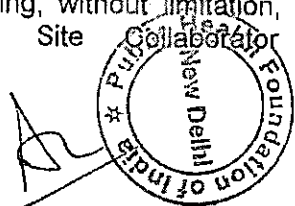
- (c) Regardless of the cause of the early termination of this Agreement and of which Party (or Parties) effects such termination, the Parties shall in all instances cooperate in closing-out of the Study at the Centre so as to ensure that the safety of the Subjects continues to be safeguarded and is not negatively affected by the Study close-out process and, without limiting the generality of the foregoing, this shall include an obligation upon all of the Parties to comply with all recommendations of the Steering Committee for closing out of the Study that relate directly or indirectly to the safety of the Subjects

- 9.2 If the Study is terminated as provided in Section 9.1, the Institution and/or the Study Site Collaborator shall be paid by PHFI for all Subject fees actually earned up to the date the Termination Notice is received by the Institution or the Study Site Collaborator and for closing-out activities in accordance with Exhibit B of this Agreement.

ARTICLE -10: INDEMNITIES, LIMITATION OF LIABILITY AND INSURANCE

- 10.1 PHFI shall hold harmless the Institution and the Study Site Collaborator and their respective officers, directors, employees, subcontractors and agents (each, an "Indemnified Party", collectively the "Indemnified Parties"), as applicable, from and against any and all claims made by third parties resulting from and against any and all liability, claims, losses, damages and expenses (collectively "Losses") that one or more of the Indemnified Parties may sustain or incur in connection with any injury, up to and including death, or any other adverse drug experiences suffered by any subject participating in the Study resulting from: (a) the administration of the study drug described in the protocol, when used in the Study in accordance with the approved labeling, the Protocol and any written instructions of PHFI provided that the Indemnified Party has (i) used prescribed and reasonable medical judgment in the conduct of the Study, (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and (iii) complied with all applicable laws and regulations and all ethical and professional standards relating to the protection of human subjects, including with respect to ensuring appropriate IRB approval and oversight, obtaining effective informed consent and maintaining subject privacy. (b) due to any grievous mistake in the protocols of the Study.
- 10.2 The Institution and the Study Site Collaborator shall jointly and severally hold harmless RCC and its officers, directors, employees, subcontractors and agents from and against any and all claims made by third parties resulting from the Institution's and/or the Study Site Collaborator (including for further certainty their respective officers, directors, employees, agents and subcontractors, as applicable) negligence or wrongful acts or omissions in connection with each of their performance or non-performance of their obligations hereunder.
- 10.3 The Institution, Study Site Collaborator and/or other Participating Centre agrees to defend, indemnify and hold harmless PHFI, from and against any and all Losses arising in connection with any injuries up to and including death or any other adverse drug experience suffered by any subject participating in the Study, to the extent caused by: (a) a breach of its obligations under the Study Agreement with PHFI, including, without limitation, the negligence or wilful misconduct of the Institution, Study Site Collaborator and/or other Participating Centre, the Site

For PHFI



Dr. V.A.Kothiwale
Registrar



investigators/Collaborator at the Participating Centre, or any of their respective employees in performing their obligations under the Study Agreement or the failure of the Participating Centre, the Study Site Collaborator at the Participating Centre, or any of their respective employees to comply with the provisions of this Agreement, the Protocol or any applicable laws and regulations; (b) the administration of the Study Drug other than in accordance with the approved labelling, the Protocol and any written instructions of PHFI concerning the administration or use thereof; or (c) the failure to provide written report within 24 hrs to PHFI/ Principal Investigator / or Sponsor any significant or alarming developments that may occur during the Study including but not limited to any subject adverse experiences.

- 10.4 Each party's obligation to indemnify the other as set forth above is conditional on the indemnified party: (a) providing written notice to the indemnifying party of any Losses for which it is seeking an indemnity for hereunder within ten (10) days after the indemnified party has knowledge of such Losses; (b) permitting the indemnifying party to assume full responsibility to investigate, prepare for and defend any such Losses; (c) assisting the indemnifying party, at the indemnifying party's reasonable expense, in the investigation and defence of any such Losses; and (d) not compromising or settling such Losses without the indemnifying party's prior written approval. In turn, the indemnifying party will not make any settlement which adversely affects in a material manner the reputation of an indemnified party without such indemnified party's prior approval, which approval shall not be unreasonably withheld.
- 10.5 PHFI/RCC have made an arrangement of insurance cover for minimum amount of Rs 5 Crores (Rupees Five Crores Only) (From Bajaj Allianz General Insurance Company Ltd. Insurance plc.) adequate to cover the risks as specified under the aforementioned provisions of this Article. However, it is understood and agreed that the maintenance of such insurance cover will not relieve either party of its other obligations under this Agreement.



ARTICLE- 11: ENTIRE AGREEMENT, AMENDMENT AND ASSIGNMENT

All schedules attached hereto and the Study Site Collaborator manual and the Protocol shall be incorporated herein as part of this Agreement. This Agreement, including the Protocol attached hereto sets forth the entire agreement and understanding of the Parties as to the subject matter herein and, other than expressly provided herein, no part of this Agreement may be modified except where agreed to in writing by the Parties. The Institution and/or the Investigator may not assign this Agreement or any obligation hereunder without the prior written consent of PHFI.

ARTICLE- 12: INVESTIGATOR AND COLLABORATOR

For the purpose of commencement of trial under this Agreement, Principal Investigators will be:

For PHFI

Page 12 of 25

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

For KLEU/JNMC




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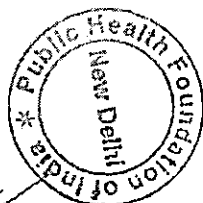
Study Site Collaborator	Principal Investigator
<p>For Institution</p> <p>Dr. M.K. Swamy, Site Collaborator DHANI, HOD OBGYN J.N. Medical College, Nehru Nagar Belgaum-590010, Karnataka, India. Phone +91-831-24094059;</p>	<p>For PHFI</p> <p>Dr. Shweta Khandelwal, Principal Investigator DHANI Associate Professor Public Health Foundation of India Plot No. 47 Sector-44 Institutional Area Gurgaon-122002 Haryana, India Phone no: +91-9891111858</p>


ARTICLE- 13: CONCLUDING PROVISIONS

- 13.1 The invalidity or unenforceability of any provision of this Agreement shall not affect the validity of any other provision hereof. The Parties undertake to make all commercially reasonable efforts to replace any such invalid or unenforceable provision with a replacement provision that is valid and enforceable and that reflects the originally intended commercial objectives of the parties as closely as possible.
- 13.2 No Party shall be responsible to the other Party(ies) for any delay in the performance of, or failure to perform, this Agreement where such delay or failure is caused by circumstances beyond the reasonable control of the affected Party(ies) including, without limitation, causes including strikes, lockouts or any other labour disruptions, war, acts of terrorism or, natural disaster. In the event of any such delay or failure in performance, the affected Party(ies) shall be granted an extension of time for performance that is equitable in light of the cause and duration of the delay.
- 13.3 This Agreement and any dispute arising hereunder, shall be governed in accordance with the laws of the State of Karnataka and with the laws of India applicable therein without reference to the conflicts of laws rules of either jurisdiction, and should it not be possible to resolve any dispute arising hereunder through good faith discussions and negotiations between the Parties, the Parties agree to attorn for the resolution of such disputes to the jurisdiction of the Courts located in State of Karnataka.
- 13.4 Articles 3, 5, 6, 10, and 13, Sections 1.5, 1.7, 1.8, 1.11, 1.12, and 4.4 and paragraphs 9.1 (c) and 9.2 shall survive termination or expiration of this Agreement.
- 13.5 If a legal person (including natural persons, incorporated entities, trusts, governmental entities, and partnerships) that is not a party to this Agreement is referred to herein for the purposes of expressly granting rights to, or confirming the rights of, that legal person, notwithstanding that the legal person is not a party hereto, it is the intention of the parties that such legal person be deemed to be a third party beneficiary with respect to the relevant provisions of this Agreement; and for further certainty, the Parties agree that such legal person shall have the right to enforce the rights expressly so granted or confirmed hereunder.

ATTESTED


For PHFI




Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



IN WITNESS WHEREOF the Parties hereto have caused this Agreement to be duly executed in three (3) counterparts, each of which shall be deemed to be an original, as of the day and year first above written.

On Behalf of Public Health Foundation of India ("PHFI")

Signature

Name: Anil Chugh-Vice President, Finance & Resources, PHFI

Date: _____

Principal Investigator

Signature

Name: Shweta Khandelwal, Principal Investigator

Date: _____

INSTITUTION:

Signature

Registrar
K.L.E University
Belgaum-590010, Karnataka, India.

STUDY SITE COLLABORATOR:

Signature

Dr. M.K.Swamy
HOD OBGYN
J.N. Medical College

Date: 2/12/15

Date: 2/12/15

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

For PHFI _____

Page 14 of 25

For KLEU/JNMC _____

Exhibit A

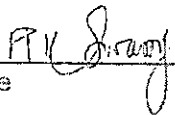
SITE INVESTIGATOR/COLLABORATOR CONFIRMATION

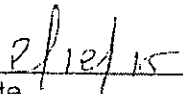
Study Name: DHANI Trial


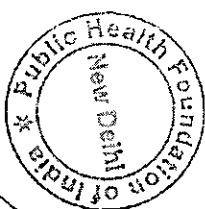
Centre #: «Site_No»


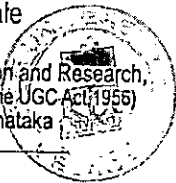
Study Site Collaborator: «Dr.» «M.K.» «Swamy»

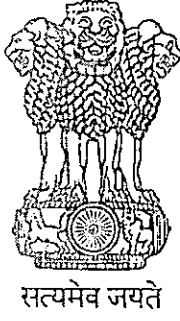
I, the Study Site Collaborator, confirm that I have received the Protocol (Version 2) dated 1st July 2015 and Manual of Procedures. I represent that I have read and fully understand the Protocol and other study related obligations. I will provide copies of the Protocol, and all information furnished by PHFI, to Sub Site investigators and other personnel participating in this Study and to discuss this material with them and ensure they are fully informed and understand the Protocol.


Signature


Date

For PHFI  

ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka
For KLEU/JNMC 



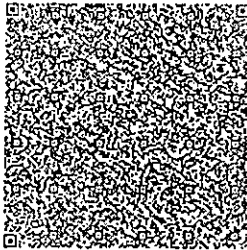
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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

Certificate No. : IN-DL78865948572629N
 Certificate Issued Date : 04-Nov-2015 08:39 AM
 Account Reference : IMPACC (IV)/ dl823003/ DELHI/ DL-DLH
 Unique Doc. Reference : SUBIN-DL82300355803506816009N
 Purchased by : PUBLIC HEALTH FOUNDATION OF INDIA
 Description of Document : Article Others
 Property Description : Not Applicable
 Consideration Price (Rs.) : 0
 (Zero)
 First Party : PUBLIC HEALTH FOUNDATION OF INDIA
 Second Party : Not Applicable
 Stamp Duty Paid By : PUBLIC HEALTH FOUNDATION OF INDIA
 Stamp Duty Amount(Rs.) : 50
 (Fifty only)



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Exhibit B

SUB-GRANT AGREEMENT

BY AND BETWEEN

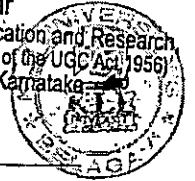
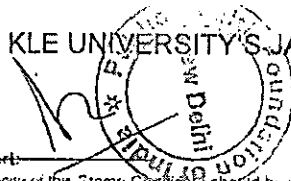
PUBLIC HEALTH FOUNDATION OF INDIA
AND

ATTESTED

Dr. V.A.Kothiwate
Registrar

KLE Academy of Higher Education and Research
Belagavi-590 010,Karnataka

KLE UNIVERSITY'S JAWAHAR LAL NEHRU MEDICAL



For PHFI

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For KLEU/JNMC

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 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.

This Sub-grant Agreement, entered into this 27th, November, 2015, between the Public Health Foundation of India (hereinafter "PHFI") and KLE University's Jawaharlal Nehru Medical College (hereinafter "JNMC") is for the purpose of conducting work related to the study entitled " Maternal DHA supplementation and offspring neurodevelopment in India (DHANI-2)" under a grant from Wellcome Trust DBT/India Alliance (hereinafter DBT/the Sponsor) has given a Grant to PHFI vide Grant No. I/CPHE/14/1/501/498 .

ARTICLE 1. ADMINISTRATIVE PERSONNEL

All questions concerning administration of this Sub-grant Agreement should be addressed to:

Dr Shweta Khandelwal
Principal Investigator DHANI
Associate Professor
Public Health Foundation of India
Plot No. 47 Sector-44
Institutional Area
Gurgaon-122002
Haryana, India

Jawaharlal Nehru Medical College contact:


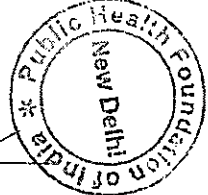
Dr.M.K.Swamy
Study Site Collaborator DHANI,
HOD OBGYN
J.N. Medical College, Nehru Nagar
Belgaum-590010, Karnataka, India.
Phone +91-831-24094059

ARTICLE 2. STUDY PERSONNEL

Dr. Shweta Khandelwal as the "PRINCIPAL INVESTIGATOR" and representative of PHFI, shall retain supervisory responsibility for this study. Any change in the scope of work requires written approval from Dr. Shweta Khandelwal. The scientific and technical direction of JNMC's portion of the research study, as set forth in the statement of work (see Appendix A, attached), shall be under the direction of Dr. M K Swamy ("Study Site Investigator Collaborator").



Study Site Collaborator is considered essential to the work performed hereunder. In the event Study Site Collaborator vacates his/her position with JNMC or is reassigned to another program, JNMC shall notify PHFI in writing. In addition, the decision to replace any individual(s) considered Key Personnel on the study at JNMC requires the prior written approval of PHFI. If this change in individual(s) considered Key Personnel is/are not acceptable to PHFI, PHFI shall issue a modification terminating this Sub-grant Agreement. JNMC will be reimbursed for its costs incurred through such termination date.

ARTICLE 3. STATEMENT OF WORK

For PHFI  

Page 17 of 25

ATTESTED


Dr. V.A. Kothiwale
Registrar

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

JNMC shall supply all the necessary personnel, equipment, and materials (except as otherwise may be provided herein) to accomplish the research tasks set forth in the statement of work (see Appendix A, attached), such work schedule being an integral part of the PHFI Scope of Work in the prime grant.

JNMC shall prepare and maintain complete and accurate records and documentation suitable for regulatory submission, in compliance with good clinical practice standards, applicable international, national, state, and local laws, rules and regulations in relation to the conduct of the Study.

ARTICLE 4. ALLOCATION OF FUNDS & AUDITS

Total money for the trial duration = INR 50,45,600

A line item budget for these funds is attached as Appendix B. JNMC's shall send an invoice to PHFI. PHFI reserves the right to request detailed expenditure documentation. A sample invoice is attached as Appendix C.

Both JNMC and PHFI acknowledge that a proposal budget is a projection and that minor changes in the proposal budget may be necessary once the study is implemented. JNMC's is required to comply with any re-budgeting requirements of the prime grantee.

Payment Timeline

All payments on the award will be made electronically via bank transfer. The India Alliance will provide funds to PHFI pro-rata on a yearly basis following the financial year (1 Apr – 31 Mar) cycle. PHFI will follow same pattern for transferring funds to KLE University / JNMC.

2% of total transferable funds are withheld from the last but one installment. Release is subject to receipt of the End-of-Fellowship Research Report and Spend Report.

The first two installments will be released in whole, regardless of the amount spent by JNMC. From the third installment onwards, if any amount from the previous year is unspent, this will be carried forward and the balance will be adjusted against the next installment.

Spend Report: To enable the release of next installment of payment; to be submitted by the JNMC. A form will be sent by PHFI Finance towards the close of the financial year. This Report must be received latest by 15 April and should detail all the expenditure undertaken on the study up to 31 March.

Funds for the next installment will not be released until a complete Spend Report is received by PHFI. PHFI will not be responsible for any delays in the release of funds if the Spend Report is not submitted in time.

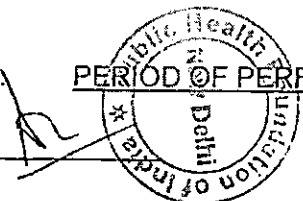
AUDITED STATEMENTS

Audited Spend Report: To indicate all the expenditures incurred on the Study during its tenure to be submitted by JNMC.

PHFI will not release the retained transferable funds unless these reports reach the office within 2 months of the end of the Study.

ARTICLE 5. PERIOD OF PERFORMANCE

For PHFI



Page 18 of 25

ATTESTED
Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to be University) U/s 3 of the UGC Act, 1956
Belagavi-590 010, Karnataka

A circular stamp of the KLE Academy of Higher Education and Research, Belagavi, Karnataka. The text around the stamp reads "KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH" and "Belagavi, Karnataka".

This Sub-grant Agreement shall become effective upon signing of the Clinical Trial Agreement and shall stay valid till the validity of the Clinical Trial Agreement itself.

ARTICLE 6. REPORTING PROCEDURES

- A. Technical Reports: JNMC's will be required to keep clear and accurate records of the procedures conducted and data collected throughout the study period so that the progress of the study may be readily evaluated at any time by PRINCIPAL INVESTIGATOR.
- B. Fiscal Reports: A final invoice of expenditures shall be made to PHFI no later than forty-five (45) days after the completion date of 1 Dec 2020.

ARTICLE 7. HOLD HARMLESS

JNMC and PHFI agree to hold each other harmless from liability of any kind including costs or expenses resulting from or on account of any or all suits or damages resulting from injuries or grievances sustained by any person(s) or property by virtue of performance of this Sub-grant Agreement except when such suits or damages arise due to the gross negligence or willful misconduct of the other party.

ARTICLE 8. REGULATORY DATA

All administrative and regulatory data required by the sponsor shall be applicable to this Sub-grant Agreement as appropriate. All conditions referenced in the prime award to PHFI by DBT shall become binding upon execution of this Sub-grant Agreement by JNMC. JNMC will submit all required original bills along with Statement of Expenditure to PHFI for reimbursement (not exceeding the sub grant amount). The expenditures by JNMC ought to conform to the budget agreed upon by the two parties (PHFI & JNMC).

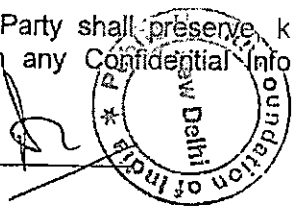
ARTICLE 9. INTELLECTUAL PROPERTY

All the Intellectual Property Rights arising out of or related to the Study and the results thereof shall be the joint property of PHFI and JNMC. By executing this Sub-grant Agreement, JNMC hereby agrees to pool data for analysis if PHFI decides to use the data for multicentric use for the consideration payable pursuant to this Sub-grant Agreement, without need for any further act or deed.

- 9.1 The term "Confidential Information" as used in this Sub-grant Agreement shall mean and include any and all information, whether written or oral, relating to each of the Parties, their respective affiliates, operations, this Sub-grant Agreement and the terms hereof, technical or commercial know-how, specifications, tools, inventions, processes or initiatives that is disclosed by a Party, its employees, agents or representatives to the other Party(ies), its employees, agents, representatives or sub-contractors in relation, or pursuant, to this Sub-grant Agreement. The term "Confidential Information" shall also include all data collected in relation, or pursuant, to the study.

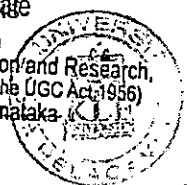
- 9.2 Each Party shall preserve, keep strictly confidential and shall not disclose to any person any Confidential Information, except to the extent that such disclosure is

For PHFI



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For KLEU/JNMC
KLE Academy of Higher Education and Research,
(Deemed to be University u/s 3 of the UGC Act, 1956)
Belagavi-580 010, Karnataka



necessary in connection with the performance of this Sub-grant Agreement or, to the extent required by applicable laws or court or administrative order. Each of the Parties further agree that they shall not use, nor permit their respective affiliates, employees, agents, representatives or sub-contractors to use, any Confidential Information for any purpose whatsoever except in the manner expressly provided or contemplated in this Sub-grant Agreement.

9.3 Each Party shall take adequate security and precautionary measures to effect compliance with this Article 9 by their respective employees, agents, representatives, sub-contractors and affiliates who are given access to any such Confidential Information. If a recipient of Confidential Information is required by law or court order to disclose Confidential Information of another Party, the recipient shall give the other Party prompt notice of such requirement so that the other Party may seek an appropriate protective order or other relief.

9.4 Notwithstanding anything contained in the abovementioned clauses, the restrictions concerning the use or disclosure of Confidential Information shall not apply to the following information:

(i) independently developed by the receiving Party or lawfully received from another source without breach of this Sub-grant Agreement; or

(ii) which is or becomes generally available to the public without breach of this Sub-grant Agreement by the receiving Party; or

(iii) which at the time of disclosure was known to the receiving Party and the fact of such knowledge was communicated to the other Party.

ARTICLE 10. PUBLICATIONS

All research reports and other publications relating to the work under this Sub-grant Agreement shall: (A) Bear proper acknowledgment of the support provided by DBT (B) Be submitted to PHFI's PRINCIPAL INVESTIGATOR in the form of advance copies for review and comment prior to publication to ensure appropriate coordination of the research results.

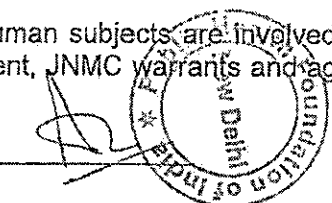
ARTICLE 11. TERMINATION

If at any time PHFI's award is terminated by DBT, this Sub-grant Agreement shall consequently be terminated upon receipt by JNMC of written termination notice from PHFI. JNMC shall be reimbursed for non-cancellable obligations incurred prior to the date of the written termination notice. PHFI reserves the unilateral right to terminate this Sub-grant Agreement upon thirty (30) days written notice for failure of JNMC to meet any substantive requirement or obligation of this Sub-grant Agreement should JNMC fail to acceptably correct the said deficiency within the said thirty (30) days or such longer period as may be mutually agreed upon by both parties. Nothing in this article is intended to abrogate the parties' right to terminate this Sub-grant Agreement on such terms as may be mutually agreed upon subsequent to the execution of this sub-grant agreement.

ARTICLE 12 HUMAN SUBJECTS

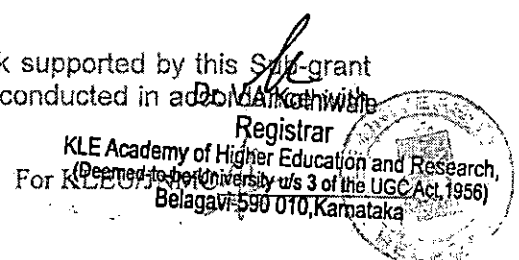
Since human subjects are involved in the conduct of the work supported by this Sub-grant Agreement, JNMC warrants and agrees that the study will be conducted in accordance with the

For PHFI



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ATTESTED



the ICH - Good Clinical Practices (GCP), ICMR and Schedule Y guidelines. Ethical guidelines for human subject protection and biomedical research like Declaration of Helsinki will also be followed. JNMC further agrees to provide certification to PHFI that an institutional committee has reviewed and approved the procedures which involve human subjects. JNMC shall bear full responsibility for the proper and safe performance of all work and services involving the use of human subjects under this Sub-grant Agreement.

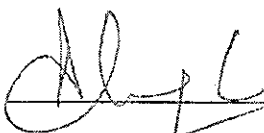
ARTICLE 13. SUBCONTRACTING

None of the activities of this Sub-grant Agreement shall be subcontracted by JNMC without the prior written approval of PHFI.

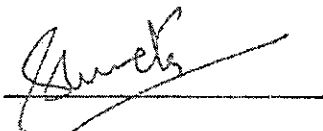
ARTICLE 14. MODIFICATION OF CONTRACT

This Sub-grant Agreement may only be modified after mutual written Sub-grant Agreement by an amendment executed through the same procedure as the original.

Public Health Foundation of India



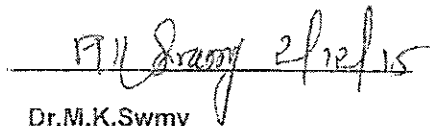
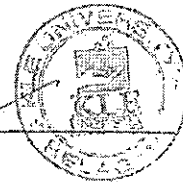
Mr. Anil Ghugh
Vice President
Finance & Resources
PHFI



Dr. Shweta Khandelwal
Associate Professor
PHFI



K.L.E University's Jawaharlal Nehru
Medical College


Registrar
KLE University

Dr. M.K. Swamy
HOD OBGYN
J.N. Medical College

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka

For PHFI _____

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For KLEU/JNMC _____

Appendix A
Statement of Work

Statement of Work

1. Obligation of the Parties

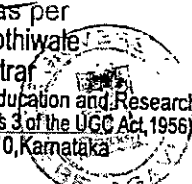
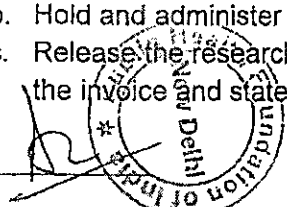
1.1 Obligations of JNMC: During the term of this Sub-grant Agreement, JNMC shall undertake the following activities under the supervision of the local Principal Investigator:

- a. Participate in the development and implementation of study Standard Operating Procedures (SOPs).
- b. Participate in regular monthly conference calls of the study steering committee (given below).
- c. Overall coordination and conducting day-to-day field work.
- d. Data collection to achieve the goals of the study as per the protocol agreed between the Parties.
- e. Adhere to standards of data collection, training and quality assurance laid down in the collaborative SOPs.
- f. Follow a systematic approach as described in the SOPs to ensure quality of data.
- g. Continuously monitor and evaluate the study to limit the risk of missed deadlines.
- h. Ensure that all clinical research is conducted according to Good Clinical Practice (GCP) and other ethic guidelines. The Institutional Review Boards shall be notified immediately of any violations of these guidelines.
- i. Establish a system of communication where adverse events are promptly reported and communicated as appropriate to the study investigators for suitable action within stipulated times
- j. Maintain inventories of study equipment and related materials such as questionnaires with timely replenishment as appropriate.
- k. Maintain storage and record of stock of study capsules and communicate in advance to the study centre (PHFI) for replenishment of stocks if the need arises.
- l. Maintain updated records of daily /weekly recruitment and disbursement of study capsules.
- m. Submit aggregate and consolidated statement of expenditure with invoice to PHFI for timely release of funds to ensure smooth functioning of fieldwork.
- n. Maintain the integrity by following common protocols and SOPs, not publishing data without approval by the study steering committee.

1.2 Obligations of PHFI: During the term of this Sub-grant Agreement, PHFI shall undertake the following activities:

- a. Support and supervise JNMC on the activities to be undertaken under this Sub-grant Agreement.
- b. Hold and administer all funds and financial operations related to the study.
- c. Release the research funds to JNMC which will be mediating the funds as per the invoice and statement of expenditure provided by JNMC.

For PHFI



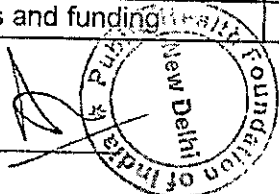
- d. Oversee all appointments of staff working on the study
- e. Pay, on a monthly basis and/or as and when appropriate, the salaries to the research team and release funds as necessary for the smooth functioning of the fieldwork in relation to the Study.
- f. Support and supervise the financial transactions under this Sub-grant Agreement.
- g. Provide overall administrative support.
- h. Create central data-bank of DHANI field work in PHFI.
- i. Coordinate and complete analyses of the data collected in the field and writing papers in peer-reviewed journals.
- j. Prepare a study report at the end of the field work, a copy of which will be kept at PHFI and JNMC.

Study Steering Committee Members

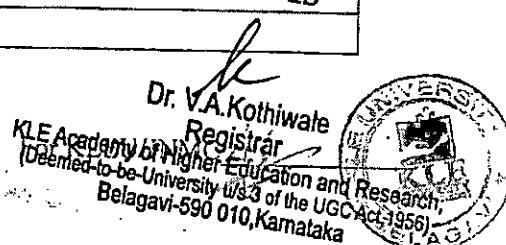
Steering Committee Members	
Roles	Team Members/Leads
Principal Investigator	Dr Shweta Khandelwal
Fellowship Supervisor	Dr. Nikhil Tandon
Mentor	Prof D Prabhakaran
Site Investigator/ Collaborators	Dr. MK Swamy and Dr B S Kodkany
Monitoring and Advisement Committee	Prof K Srinath Reddy Dr Reynaldo Martorell Prof Nikhil Tandon (Fellowship Supervisor – India) Prof Aryeh Stein (Fellowship Supervisor – US) Dr Usha Ramakrishnan Prof D Prabhakaran (Mentor) Dr Gauri Divan Prof R Lakshmy
Data Safety and Monitoring Committee	Dr Vinod Paul (Chair) Dr Aiyagiri Rao Dr. RM Pandey Dr. Sonia Naik Dr. Anita Saxena
Biostatistician	Dr. Dimple Kondal
Project Officer JNMC	Ms. Ganga Pujeri
Data Management	Mr Naveen Kaushik
Biochemical Analyses and training	Dr Ruby Gupta
Coding, Randomization and packing supervision	Ms Divya Soni
Finances and funding	Not assigned yet

ATTESTED

For PHFI



Page 23 of 25



Appendix B
Budget

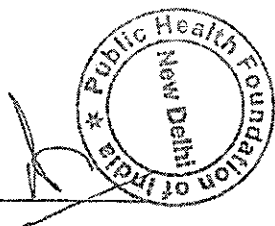
Approved budget for JNMC

S.No.	Heads	Cost per month	Duration	Total Cost to be paid
	JNMC			
1	Staff salaries			
	Project officer	18000	5 years	1080000
	Field worker 1	15000	4 years	720000
	Field worker 2	15000	4 years	720000
	Technician/Nurse	Lumpsum	5 years	500000
	Total			3020000
2	Access Charges	Lumpsum	5 years	55000
3	Miscellaneous			
	Stationery, internet, courier costs	Lumpsum	5 years	100000
	Neurodevelopment psychologist consultancy	Lumpsum	4 years	50000
	Mother and Child Visits	Lumpsum	5 years	700000
	Local conveyance and adverse event trips	Lumpsum	5 years	100000
	Travel allowance for project officer	8000	5 years	480000
	Total			1430000
	SUBTOTAL (1+2+3)			4505000
	Overheads (12%)			540600
	Grand Total (INR)			5045600

(Fifty lakhs forty five thousand and six hundred only)

ATTESTED

For PHFI



Page 24 of 25

Dr. V.A. Kothiwate
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka
For KLEU/JNMC

Appendix C Sample Invoice

SAMPLE FORMAT

	YOUR INSTITUTION ADDRESS TELEPHONE/FAX	
TO Public Health Foundation of India TOWER NO 4, C-3 COMMERCIAL COMPLEX, VASANT KUNJ NEW DELHI, 110070, INDIA		INVOICE DATE (YOUR ACCOUNT IDENT. FIRM) INVOICE#
CONTACT/CARD NO. REIMBURSABLE EXPENSES FOR 1 AMOUNT FOR THE CURRENT PERIOD	NOT-EX-XXXX THRU ISR	
	CURRENT EXPENSES	CUMULATIVE EXPENSES
SALARY/WAGES		
FRINGE BENEFITS		
CONSULTANTS		
COMMUNICATIONS		
SUPPLIES		
TRAVEL		
EQUIPMENT		
ASSISTANT COORDINATOR CHARGES		
PATIENT		
OTHER		
TOTAL DIRECT COSTS		
INDIRECT COST % of		
TOTAL EXPENSES		

The subcontractor hereby certifies that the costs for which reimbursement has been solicited and/or is requested under the subcontract are actual costs as recorded on the subcontractor's records, and any rates used in these bills are the government approved rates. The records supporting these are available for inspection and audit as required by the contractor's prime agreement representatives.

CERTIFIED CORRECT BY:

NAME
TITLE

For PHFI



Page 25 of 25

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

For KLEU/JNMC





भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

No. 5/4/5-6/Diab.16-NCD-II

Dated: 14.06.2018

To,

✓ Dr. Harpreet Kaur
Assistant Professor
Department of Physiology
J.N Medical College, Belgaum (Karnataka)-590010

Sub: Evaluation of the effect of structured exercise therapy on neurophysiological and cognitive functions of young adults with type 2 diabetes mellitus.

Madam,

----- Please refer to the enclosed letter for details.

The Competent Authority of the ICMR has decided to continue the above mentioned project in 2nd year w.e.f 15.03.2018 to 14.03.2019 with the budget of Rs. 3,18,415/- (Rupees three lakh eighteen thousand four hundred fifteen only). A copy of the budget statement is enclosed herewith. The other terms and conditions will remain same as mentioned vide this office letter of even number dated 09.03.2017.

Yours faithfully

(Sushila Kargaonkar)
Sr. Admn. Officer

Copy to:-

1. The Principle, Jawaharlal Nehru Medical College, Nehru Nagar, Belagavi-590010, Karnataka
2. Accounts Section (RFC No. (P-20) NCD/Ad-hoc/24/2016-17 dated 09.02.2017
3. IRIS Cell
4. Mr. Hemant, Sr. TO, ICMR
5. Sr. A.O. NCD

For Director General
ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Budget Statement for the Period
(w.e.f. 15.03.2018 to 14.03.2019)

No. 5/4/5-6/Diab.16-NCD-II

Ad-hoc

Subject: "Evaluation of the effect of structured exercise therapy on neurophysiological and cognitive functions of young adults with type 2 diabetes mellitus" under Dr. Dr. Harpreet Kaur, J.N Medical College, Belgaum.

S. No	Item	2 nd Year
A.	Staff	
	Lab Assistant @ Rs. 17,760/- (5200+2400=7600x10%=760)	2,13,120
B.	Contingency	
	Recurring	
	Test	46,870
	Case Performa Printing	2,000
	Questionnaire Printing	2,000
	Communication Charges	2,500
	Data Entry Charges/Data Management Charges/Data Analysis	20,000
	Preparation of research report	7,000
	Office Supplies	5,000
	Total	2,98,490
	Overhead charges 5%	14925
C.	Travel	5,000
	Grand Total	3,18,415

(Rupees three lakh eighteen thousand four hundred fifteen only)

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

REGISTRATION NO. / 1303

02 AUG 2017

Faded text, likely a certificate or official document header.

Table with multiple columns and rows, containing illegible text and numbers.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education

Sl. No.	Particulars	Estimated	Actual
1	Salaries (Staff)	5,00,000/-	5,00,000/-
2	Recruiting Expenditure	24,26,000/-	24,26,000/-
3	Contingencies, Miscellaneous	12,000/-	12,000/-
4	Travel	53,000/-	53,000/-
5	Books & Stationery	24,000/-	24,000/-
6	Grand Total	29,15,000/-	29,15,000/-

1. The project is approved under the CRAS Research Policy of the Government of Karnataka. The project is being implemented by the participating institutes, namely, KLE Academy of Higher Education and Research, Belagavi, and the Government College, Belagavi. The project is being implemented under the CRAS Research Policy of the Government of Karnataka. The project is being implemented by the participating institutes, namely, KLE Academy of Higher Education and Research, Belagavi, and the Government College, Belagavi.

2. The progress of the project is reported to the project committee in the prescribed format (Annexure - I to CRAS Research Policy). The final report should be submitted in the prescribed format (Annexure - II to CRAS Research Policy) within two months from the date of completion of the project. The project committee shall submit the final report to the project committee.

3. The project committee shall submit the final report to the project committee. The project committee shall submit the final report to the project committee.

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11. The project committee shall submit the final report to the project committee. The project committee shall submit the final report to the project committee.

12. The project committee shall submit the final report to the project committee. The project committee shall submit the final report to the project committee.

ATTESTED

 Dr. V. A. Kothiwala
 Registrar

KLE Academy of Higher Education and Research
 (Deemed to be University) 693 of the UGC Act, 1956
 Belagavi-590 010 Karnataka



Karnataka Science and Technology Promotion Society

Belagavi-590 010, Karnataka
Karnataka Science and Technology Promotion Society
Belagavi-590 010, Karnataka
Karnataka Science and Technology Promotion Society
Belagavi-590 010, Karnataka

Belagavi-590 010, Karnataka

Greetings from the Dept of Information Technology, Science and Technology

We are pleased to inform you about the establishment of Microbiology Skills Laboratory to Enhance Teaching-Learning and Assessment of Essential Skills in Medical and Paramedical Students. The project is funded by CISEE for the financial year 2016-17. The project is approved on the recommendations of Visiting Committee and the Chairmanship of Prof. CNR Ray, H. O. D. of the Department.

The total project grant award for a period of 3 years will be released annually @ Rs. 10.00 lacs. The institution is requested to take an immediate action to initiate the project within 3 years after receiving the cheque of 10 lacs.

The grant will be paid to the Head of the Institution. The Principal Investigator shall be responsible for completion of the stated objectives of the project. The Principal Investigator through the Institution should submit the progress report in soft copy (word & pdf) and hard copy to the office. The grants shall be used only for the purposes described above and by following due procedures of KTPP Act. Any deviation from the project must have a prior approval from the VGST. A sample copy of the project is enclosed for information and necessary action in the future.

Future releases of grants will be based on satisfactory project progress. The funding agency has the right to terminate the project if it is found to be not satisfactorily pursuing and fulfilling the stated project goals and objectives.

ATTESTED

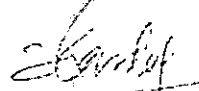
Department of Science and Technology
Department of S&T, Karnataka Government
New Office Building - Floor 4 - Side
17-B Building, Dr. Ambedkar Road,
Bangalore - 560007

Phone: 082 2203 2013
Email: info@stisat.gov.in
Website: www.stisat.gov.in

I want to personally thank you for being selected as one of the 1000 program members and we wish you and the Principals of participating great success in the implementation of the project.

Thanking you

Yours sincerely,



(H. Honne Gowda)

To:
The Principal
Jawaharlal Nehru medical college,
INMC KLE University Campus, Nehru Nagar,
Belagavi, Karnataka 590010

CC:

Dr. Ayoti, M. Nagamoti, Program Coordinator, Dept. of Microbiology, Jawaharlal
Nehru medical college KLE University, Belagavi 590010.

ATTESTED



Dr. V.A. Kothiwale
Registrar

Director of Higher Education and Research,
Government of Karnataka, 3rd floor, UGC, 1950



DEPARTMENT OF HEALTH AND FAMILY WELFARE
KARNATAKA STATE AIDS PREVENTION SOCIETY
Sir. C.V. Raman General Hospital, 2nd Floor, 80 feet Road, Indiranagar, Bengaluru-39

No: KSAPS/Lab Services/Viral Load02/2017-18

Date: 31.03.2018

RELEASE ORDER (GFATM FUND RRC-IV)

Sub: Payment of advance for 9 SRL Centres towards setting up
Viral Load Lab - reg

Ref: Approval by PD para no.(23) Date: 31.03.2018

Approval is accorded for payment of Rs.46,50,000/- (Rupees Forty Six Lakhs Fifty Thousand only) towards 9 SRL Centre's as mentioned below towards setting up Viral Load Laboratory:

Sl.No	District	Name of the ART Centres	Bank Account No.	IFSC Code No.	Advance
1	Bangalore	BB NIMHANS, BANGALURU KAR	64026237300	SBIN0040675	600,000
2	Bangalore	Dept of Microbiology Victoria hospital bangalore medical college	54018114189	SBIN0070242	600,000
3	Bellary	Dept of Microbiology, Vijayanagar institute of medical science Bellary	64051136253	SBIN0040456	600,000
4	Hubli	SRL Dept of Microbiology Karnataka Institute of Medical Sciences Hubli	64017454406	SBIN0040493	600,000
5	Belgium	SRL Dept of Microbiology JN Medical College Belgium (Private)	05042010064815	SYNB0000504	350,000
6	Bijapur	Dept of Microbiology BLDEU sri patil medical college Bijapur (Private)	64019705415	SBIN0014429	350,000
7	Mysore	SRL Dept of Microbiology JSS Medical College Mysore (Private)	64137295345	SBIN0040547	350,000
8	Gulbarga	DAPCU Gulbarg	30341210643	SBIN0003304	600,000
9	Shimoga	DAPCU Shimoga	64026236533	SBIN0040580	600,000
TOTAL					46,50,000

[Handwritten Signature]
UNTESTED

Dr. V.A.Kothiwale
Registrar

The advance is released under Global Fund IV under Component 2.2.6 - subject to the following conditions:

1. The Amount released shall be utilized for the same purpose for which it has been released.
2. Programme Officer shall communicate the Component wise allocation.
3. The Expenditure shall be incurred as per the guidelines issued by KSAPS.
4. The Expenditure shall be limited to the component wise budget allocation communicated by KSAPS.
5. Excess expenditure incurred (if any) under any of the activities will not be admitted.
6. The unspent of the advance if any, shall not be utilized for un approved activities and the unspent amount and the interest accrued on SB account shall be remitted back to KSAPS by PFMS only.
7. Utilization Certificates and Statement of Expenditure duly certified by AMO's shall be submitted to Finance Section of KSAPS.
8. All the Payments shall be made in PFMS only.

Assistant Director (Finance)
KSAPS, Bangalore

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



080 - 2528143
Fax 080 - 25281430
E-Mail:
jdflinksaps@gmail.com

DEPARTMENT OF HEALTH AND FAMILY WELFARE
KARNATAKA STATE AIDS PREVENTION SOCIETY

Sir C.V Raman General Hospital, 2nd Floor 80 Feet Road, Indiranagar, Bengaluru-38.

No.KSAPS/Eab Service/Viral/load/02/17-18

Date:29.03.2019

RELEASE ORDER (DBS FUND)

Sub: Release of advance towards Setting up Viral Load at SRL's for the year 2018-19

Sanction is accorded for payment of Rs 10,50,000/- (Rs Ten lakhs thousand only) to Institution as mentioned below through PFMS to their concerned SB accounts towards Setting up Viral Load at SRL's.

Sl No	Name of the SRL	Name of the Account Holder	A/c No	Total Amount
1	Dept of Microbiology, JN Medical College, Belgaum	M's ICHAP Project	05042010063815	350,000
2	Dept. Microbiology, BLDEU's Shri BM Patil Medical College, Bijapur	SRL Department of Microbiology	37595420172	350,000
3	Dept. of Microbiology, JSS Medical College, Mysore.	State Reference Laboratory	54137295345	350,000
		Total		1,050,000

The advance is released under DBS Fund subject to the following conditions:

- 1 The amount released shall be utilised for the same purpose for which it has been released.
- 2 The programme officer shall communicate the component wise budget allocation to the concerned.
- 3 The expenditure shall be limited to the component wise budget allocation communicated by KSAPS.
- 4 Excess expenditure incurred (if any) under any of the activities will not be admitted.
- 5 It is instructed to operate the funds through PFMS as per Circular No. KSAPS/JD(F)/PFMS/2016-17 dated 09.10.17 and the unspent amount of grant released including the Interest accrued on the account shall be returned back to KSAPS through PFMS only.

ATTESTED
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 6 The UC and monthly SOE submitted to KSAPS should clearly specify under which fund the amount was released and Utilised along with the original Bills or certified bills & Vouchers by grant utilizer
- 7 State Programme Officers shall certify on the Utilisation certificates and statement of Expenditure and confirmation of the programme on which purpose fund released then submitted to finance section.
- 8 The advance Settlement within One month from the date of release of advance.
- 9 The unspent amount should be remitted to KSAPS Account No 64094979930 through PFMS with out fail, acknowledgement of PPA sent to KSAPS through mail. With out acknowledgement of PPA we are unable to receipt of unspent amount

PPA NO C031933660625 dt.29.03.2019 Rs.3,50,000/-
PPA NO C031933929020 dt.29.03.2019 Rs.7,00,000/-

Assistant Director(Finance)
KSAPS, Bangalore

Copy & Necessary action

- 1 Additional Project Director, KSAPS Bangalore
- 2 Quality Manager Lab Service, KSAPS, Bangalore
- 3 All District AIDS Prevention and Control Units (DAPCUs)
- 4 Office Copy

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2018(1)

दूर सूचना/सूचना/सूचना 26588980, 26588707, 26589336, 26589745, 26589414
फैक्स/फैक्स 011-26588662, 011-26589791, 011-26589258

तार / GRAM विज्ञानी / SCIENTIFIC
वेब-साइट www.icmr.nic.in
ई-मेल icmrhqds@sansod.nic.in



icmr
INDIAN COUNCIL OF MEDICAL RESEARCH

भारतीय आयुर्विज्ञान अनुसंधान परिषद INDIAN COUNCIL OF MEDICAL RESEARCH

वी. रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
V. RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

Dr. N. C. Jain
Scientist- G & Head (HRD)

No.3/2/March- 2019/PG-Thesis-HRD (36)
Dated: 25.03.2019

Dr. Karthika Christina Susmita,
Community Medicine,
JNMC, Belagavi-590 010
christikarthaka20@gmail.com

Dear Dr. Karthika Christina Susmita,

This is with reference to your application seeking financial assistance from the ICMR for MD/MS/DM/MCh dissertation thesis entitled "Profile of married women with infertility residing in rural area".

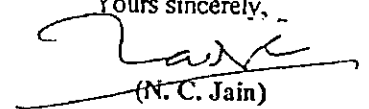
I am glad to inform you that Director General, ICMR, based on the recommendation of Expert Committee, has sanctioned a sum of Rs. 50, 000/- (Fifty thousand only) for providing an electronic and hard copy of your dissertation thesis to the ICMR. Mandatory requirement to avail this opportunity is to provide us with an undertaking duly forwarded through the guide, to the undersigned, enabling us to release the grant.

This is to inform you that Rs.50, 000/- will be disbursed to you in two instalments. Initial amount of Rs.30,000/- after receipt of the undertaking as per the guidelines and remaining amount of Rs.20,000/- on receipt of the electronic copy, hard copy and summary of work done of your dissertation thesis duly approved by the University/ Institute along with one publication in an indexed Journal.

The amount will be released after submission of the UNDERTAKING AS WELL AS THE MANDATE FORM (format enclosed) WITHIN SIX WEEKS for receiving e-payment along with a photocopy of a cancelled cheque for purpose of verification of the concerned bank account where money is to be remitted.

Kind regards,

Yours sincerely,


(N. C. Jain)
011-26589258
drencejain@gmail.com

Copy to: Dr. Padmaja R Walvekar, Professor, Community Medicine, JNMC, Belagavi-590010.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Invdt Award of ICMR Short Term Studentship for the year 2018

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
Belagavi-590 010, Karnataka

Open to ALL the students of the institution
Date: 15th October 2017
Subject: Research in any field of Science, Technology, Humanities and Social Sciences
Term: 02 months

Dear Sir/Madam,

I am pleased to inform you that you are eligible for ICMR Short Term Studentship for the year 2018. The award is for a period of 02 months with a stipend of Rs. 15,000/- (i.e. Rs. 5000/- per month) for any two months (between April to July, 2018) on the proposed research project. The award is subject to conditions and approval of report by ICMR. Kindly complete the research at the earliest, so that the report can be prepared and submitted on time.

Please ensure that your report shall be considered/accepted only upon the date of 15th October 2018.

The research carried out by the student must be in compliance with ICMR Guidelines for Ethical Clearance of *Biomedical Research on Human Participants, 2017* and *National Ethical Guidelines for Biomedical Research Involving Children*, which may be downloaded from ICMR website (http://www.icmr.gov.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf) http://www.icmr.gov.in/guidelines/National_Ethical_Guidelines_for_Biomedical_Research_Involving_Children.pdf

Please Note If the work involves human participants, then a clearance from the Institutional Ethics Committee (IEC) must be obtained along with an informed consent from the subjects recruited for the study. Also note that studies involving stored samples/ human biological material/ retrospective analysis of record/ surveys etc, also require clearance from IEC. If the work involves use of an animal, then a clearance must be obtained from the Institutional Animal Ethics Committee (IAEC). Research should not be undertaken unless cleared by the IEC committee. In case it is felt that research belongs to exempt category a "Certificate of Exemption" may be obtained from the IEC.

On completion of the studentship, a report of the actual work done may please be submitted ONLINE as per detailed format and instructions specified on ICMR website. It is advised that prior to writing the report, please go through all the instructions loaded by ICMR thoroughly. The report must contain the following: Review of Literature, Aims and Objectives, Material and Methods, Observations and Results, Discussion, Conclusions & Bibliography and must be submitted ONLINE before the last date. Period of acceptance of reports will NOT be accepted. Without appropriate clearances from ICMR/C, the report will not be accepted.


The ICMR has invited this programme to provide opportunity to all the students who are engaged in the field of research techniques, methodology and also with preparing reports. It is expected that ICMR will provide financial support and guidance to the students in their endeavor. Further information about the programme and the submission as well as the last date for submission is provided on ICMR website. The students who are engaged in the project work to carry out possible in any two months between April to July, 2018 and submit the report on or before 15th October 2018. The date to submit the report will be between 1st August 2018 to 15th October 2018, however, it is advised that the updated instructions of ICMR should be followed. It may please be followed.

In case of any queries, please send email at ststud2017@gmail.com

Wishing you all the best.

(Mrs. Harjeet Desai)
Administrative Officer-STE
(For Director General)

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

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Second block of faint, illegible text, appearing to be the main body of a letter or report.

Third block of faint, illegible text, continuing the main body of the document.

Fourth block of faint, illegible text, likely a concluding paragraph or signature area.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



सी.एस.आई.आर. जीनोमिकी और समवेत जीवविज्ञान संस्थान
(वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद, भारत सरकार)
दिल्ली विश्वविद्यालय परिसर, माल रोड, दिल्ली-110007 भारत

CSIR-Institute of Genomics & Integrative Biology

(COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH, GOVT. OF INDIA)
DELHI UNIVERSITY CAMPUS, MALL ROAD, DELHI-110007, INDIA

No. PD/TRISUTRA/TFC/2012
Dated: 18 December 2012

To
The Principal
KLE University's Shri BM Kankanawadi Ayurveda Mahavidyalaya
Belgaum
Karnataka

Sub: Transfer of funds for the project titled "Identification of genomic correlates of *Prakriti* in Healthy Individuals from Dravidian population of North Karnataka"

Respected Sir,

I am to refer to your proposal for the aforesaid project and to convey approval of budget, initially for a period of three years, as per details given below:

S No.	Details	1 st Year	2 nd Year	3 rd Year	Total (INR)
1	Prakriti analysis, Oral DNA sample collection, detailed phenotyping and sample collection	2200000	1600000	600000	4400000

This sanction is subject to review of periodical progress of the project by CSIR Ayurgenomics Unit.

CSIR Ayurgenomics Unit has further been pleased to release 50 per cent of the budget for the current year amounting to Rs.11, 00,000.00 (Rupees Eleven lakh only). The budget for the next financial year would be released on or after 1st April, 2013 after review of progress based on milestones of the project.

Sanction of funds is subject to strict compliance of the terms and conditions enclosed which may be as amended/modified from time to time. The expenditure on this account will be debited to budget head MLP-901

20 DEC 2012

Encl. As above

Yours sincerely,

Mitali Mukerji
(Mitali Mukerji)

Inward No. 2121 Sign.

Copy: 1. Dr. KS Prasad, KLE University's Shri BM Kankanawadi Ayurveda Mahavidyalaya, Belgaum, Karnataka
2. F&AO, CSIR-IGIB, Delhi

ATTESTED

Dr. V.A. Kothiwale
Registrar

Tel. : 91-11-27667602, 27666156-157, 27667439 • Fax : 91-11-27667471
Telefax : 91-11-27662407-08, 27662099 • E-mail : info@igib.res.in
KLE Academy of Higher Education and Research,
(Deemed to be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Terms and Conditions:

1 The first installment of funds will be utilized subject to submission of the following documents/information:

- Acceptance of the funds sanctioned as above
- The project should start immediately.

2. While claiming funds for the subsequently year(s), the position regarding unspent balance of the previous year must be mentioned in the bill. Statement of Account, duly audited by the Accounts Officer and countersigned by the next higher authority, in respect of the funds received and expenditure incurred along with balance, if any, during the previous year should also be invariably enclosed with the bill.

3. Utilization of funds and maintenance of account under the specific heads should be in accordance with the procedure laid down by the KLE University's Shri BM Kankanawadi Ayurveda Mahavidyalaya/CSIR.

4. Your obligation under this sanction includes, inter alia, the following:

- > To submit Annual Progress Report to CSIR Ayurgenomics Unit by 1st April of each financial year positively; and
- > To submit Audited Statement of Accounts along with Audited Utilization Certificate from the appointed Chartered Accountant/Accounts of the receiving Institute for the funds transferred by CSIR Ayurgenomics Unit on termination of the project.

5. All instruments/equipment purchased out of funds provided by CSIR Ayurgenomics Unit will be the property of CSIR Ayurgenomics Unit (TRISUTRA) and shall clearly be labeled as "CSIR-TRISUTRA Property". CSIR-TRISUTRA shall, on completion of project, will decide about location of its property.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/GS/12/01

Protocol Title: "Identification of genomic correlates of Prakriti in Healthy individuals from Dravidian population of North Karnataka"		
Principal Investigators at IGIB: Principal Investigator at BMK Co-investigators: Dr. Mitali Mukerji, Dr. B. S. Prasad, Dr. Shivakumar Harti Dr. Bhavana Prasher, Dr. Supriya Bhalerao		
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya & KLE Ayurved Hospital, Shahapur, Belgaum		
<input type="checkbox"/> New Review	<input checked="" type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review
Date of Review (DD/MM/YY): 03.06.2014		
Date of previous review, if revised application: 10.11.2012., 3.6.2013		
Name of the Reviewers who attended the meeting: Dr. Subarna Roy, Dr. C. R. Gaikwad, Dr. S. K. Hiremath, Dr. R. A. Udupudi, Dr. N. M. Hampannavar, Shri Anil Bagi, Shri Neminath Kunne, Shri Antin M. C., Dr. Amit J. Kamate		
Decision of the the Ethics Committee:		
Recommended <input checked="" type="checkbox"/>	Recommended with suggestions <input type="checkbox"/>	
Revision <input type="checkbox"/>	Rejected <input type="checkbox"/>	

ATTESTED

Page 1 of 2

Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Suggestions/ Clarifications / Reasons/ Remarks:


Following are the suggestions/clarifications of the EC- NIL.

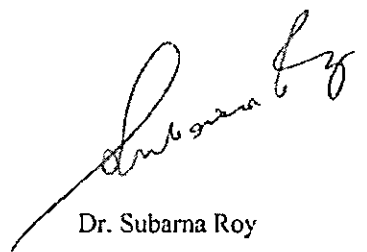
Ethics committee needs to be informed in case of any protocol deviation

Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse


Dr. Basavaraj R Tubaki
(Member Secretary)


Dr. Subarna Roy
(Chairperson)

ATTESTED Page 2 of 2


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010,Karnataka



Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/GS/12/01

Protocol Title: "Identification of genomic correlates of Prakriti in Healthy individuals from Dravidian population of North Karnataka"		
Principal Investigators at IGIB: Principal Investigator at BMK Co-investigators: Dr. Mitali Mukerji, Dr. B. S. Prasad, Dr. Shivakumar Harti Dr. Bhavana Prasher, Dr. Supriya Bhalerao		
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya & KLE Ayurved Hospital, Shahapur, Belgaum		
<input type="checkbox"/> New Review	<input checked="" type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review
Date of Review (DD/MM/YY): 03.06.2015		
Date of previous review, if revised application: 10.11.2012., 3.6.2013, 3.6.2014		
Name of the Reviewers who attended the meeting: Dr. Subarna Roy, Dr. C. R. Gaikwad, Dr. S. K. Hiremath, Dr. R. A. Udupudi, Dr. N. M. Hampannavar, Shri Anil Bagi, Shri Neminath Kunne, Shri Antin M. C., Dr. Amit J. Kamate		
Decision of the the Ethics Committee:		
Recommended <input checked="" type="checkbox"/>	Recommended with suggestions <input type="checkbox"/>	
Revision <input type="checkbox"/>	Rejected <input type="checkbox"/>	

ATTESTED

Page 1 of 2


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Suggestions/ Clarifications / Reasons/ Remarks:

Following are the suggestions/clarifications of the EC- NIL

Ethics committee needs to be informed in case of any protocol deviation

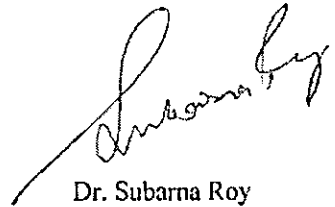
Recommended for a period of :One Year

Please note *

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- Inform EC in case of any change of study procedure, site and investigator
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- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
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- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse



Dr. Basavaraj R Tubaki
(Member Secretary)



Dr. Subarna Roy
(Chairperson)
ATIESIED

Page 2 of 2



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Financial Management System - PFMS

Department of Accounts, Ministry of Finance

Version: 1.0
 Controller: sbhatteje
 User Type: P
 Financial Year: 2015-2016

- Home
- Dashboard
- Reports
- Sanctions
- Sanction History
- Sanction Details
- Sanction Templates
- Sanction Templates
- Reports
- Masters
- My Schemes
- Scheme Allocation
- Register / Track Issue
- CPSMS Forum
- OLD UC

Controller: 017 HEALTH AND PUBLIC WELFARE

Sanction Number: 229873/01/2015/11/11

Sanction Type: Transfer (B) (1) (1)

IFD Number: 11/70

Plan Scheme: 0132-AYUSH AND PUBLIC HEALTH

DDO: 229873 DEPT. OF HEALTH, RED CROSS BUILDING, NEW DELHI

Sanction Status: Approved

Sanction Date: 01/07/2015

Sanction Amount: 1000000.00

IFD Date: 01/07/2015

PAO: 01/07/2015 PAO (Sanction) Ministry of Health & Family Welfare

Remarks: Sanction entered successfully, not approved.

Created By: sbhatteje

Created On: 01/07/2015 02:10:15

Modified By: sbhatteje

Modified On: 01/07/2015 10:10:15

Account Details:

Grant: 006-M/o of Ayurveda, Yoga & Naturo, Unani, Siddha & Homeo

Function Head: 2160.0002806 AYUSH AND PUBLIC HEALTH

Object Head: 31-GRANTS-IN-AID

Category: 9-PLAN VOTED-EXPENDITURE

Agency Details:

Agency Code	Agency Name	Agency Address	Agency City	Agency State	Agency Pin	Agency Contact
1	Dr. V. A. Kothiwale Lankavadi Ayurved Mahavidyalaya Belgaum	Belgaum	BELGAUM	KARNATAKA	591111	0231-241111

Handwritten:
 R. K. KAPRI
 Under Secretary
 Ministry of Health, Govt of India
 Atal Bihari Vajpayee EPB Complex
 New Delhi-23

ATTESTED

Sanctioned successfully (But S/MC has not been sanctioned in network yet)

Handwritten Signature:
 Dr. V.A. Kothiwale
 Registrar
 KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

To
The Pay & Accounts Officer (Pay),
Ministry of Health and Family Welfare,
Government of India,
Ayush Bhawan, New Delhi - 110 011.

Subject: Proposal from "Shri B. M. Kankanwadi Ayurved Mahavidyalaya", Belgaum, Karnataka under the Central Sector Scheme for Grant-in-aid Scheme for Promotion of AYUSH Intervention in Public Health Initiatives during 2015- 2016 (Plan).

Sir,

I am directed to convey that your proposal entitled "Creating sustainable solutions to address Anaemia in school children of Rural area (Schools under Primary Health Centre, Hudali of Belgaum District, Karnataka) through Ayurveda" has been approved in the meeting of the Project Sanctioning Committee for the total grant of Rs. 1,23,10,145/- (Rs. One Crore twenty three lakhs ten thousand one hundred forty five only) for the period of three years. I am further directed to convey the sanction of the President for release of 1st installment of Rs. 49,24,000/- (Rs. Forty nine lakhs twenty four thousand only) to "Shri B. M. Kankanwadi Ayurved Mahavidyalaya", Belgaum, Karnataka for undertaking the above mentioned project under the Central Sector Grant-in-Aid Scheme for Promotion of AYUSH Intervention in Public Health Initiatives during 2015- 2016. This is a non-recurring grant (Plan).

2. The first installment is being released for the project involving the following activities by the organization and progress report should be furnished on the basis of the following deliverables and on following conditions:-

- Assess the health status of the students
- Identify health problems related to anaemia and its management.
- Assist with the development of positive health attitude and practices in school children.
- To identify problem areas in school environment and to assist with corrective measures.
- Capacity building programmes for students, parents, teachers, local health care staff on the following topics:
 - Personnel hygiene and Promotion of Positive health of Children
 - Nutrition and health
 - Prevention of Communicable diseases
 - Usage of medicinal plants in the preventing, curing of diseases and promotion of health.
 - Healthful school environment (Hygiene etc.)
 - Family life (Sadvratta)

(f) The administrative cost of the project will be Rs. 3.00 lakhs for the period of three years.

(g) Travel expenses will be restricted to Rs 300 / day. Accordingly, the total travelling cost for the period of three years will be Rs. 2,70,000/-.

3. The Grant-in-aid will be subject to the conditions laid down in the rules 206 to 215 of General Financial Rules 2005 as amended from time to time and the provisions of Central Sector Scheme for Promotion of AYUSH Intervention in Public Health Initiatives.

4. It is further stipulated that, the grantee institutions will submit Expenditure Statement, Utilization Certificate, Audited Statement of Accounts in respect of grants released and Achievement-cum-Performance report of the project within twelve month after issue of sanction.

5. The Ministry has decided to release the sanctioned grant on the following conditions:-

ATTESTED

[Signature]
Under Secretary
Ministry of Health and Family Welfare
Government of India

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Chief of the Institution shall be personally accountable for proper utilization of grant.

The provisions contained in the Scheme should be complied with and no deviation from a provision of scheme should be made. Grant in aid shall be utilized for the purpose of the scheme during the duration specified for the activity.

- III The grantee Institution shall maintain a separate account of grant received in a scheduled Nationalized Bank in the name of the organization
- IV The Audited statement of accounts should be furnished after utilization of grant in aid or whenever called for.
- V The Grantee Institution will submit a six monthly achievement-com-performance report of the progress of work to the Ministry of AYUSH
- VI The Grantee organization shall maintain the record of assets required wholly or substantially out of the grant and these shall not be disposed off without prior approval of the Government

6 The Accounts of the Grantee Institution / Organization shall be open to inspection by the Sanctioning Authority and Audit, both by the Comptroller and Auditor General (CAG) of India under the CAG (DPC) Act, 1971 and Internal Audit Wing of the O/o CCA of the Ministry, whenever the Institution or Organization is called upon to do so.

7 The Grantee shall not divert the grants or entrust the execution of the scheme to another Institution / Association and shall abide by the terms and conditions of grant. If the grantee fails to utilize the grant for the purpose for which the same has been sanctioned, the grantee will be required to refund the amount of the grant with interest thereon at 10% per annum as applicable from time to time under the provisions of GFR.

8 There is no reason to believe that the grantee is involved in corrupt practice.

9 The amount of Rs. 49,24,000/- (Rs. Forty nine lakhs twenty four thousand only) is debitale to the Demand No.006 - Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy, 2210-Medical & Public Health (Major Head), 02200 -Other Systems (Minor Head), 28 -Ayush & Public Health, 280031-Grant-in-aid- General (Plan) during 2015-16.

10 It is certified that the Grantee organization is not a defaulter in submission of utilization certificates.

11 This sanction issues with the concurrence of Finance Division vide their concurrence Dy. No. C-79, dated 22/04/2015.

Yours faithfully,

N. Khatri

Under Secretary to the Government of India
Ministry of AYUSH, GPO Complex
AYUSH Bhawan, B-Block, GPO Complex
INA, New Delhi-23

Copy forwarded for information and necessary action to:-

- 1 The Director General of Audit, Central Revenues, I.P. Estates, New Delhi -110002.
- 2 The Principal, Shri Kankanwadi Ayurveda Mahavidyalaya, Shabapur, Belgaum, Karnataka - 590003
- 3 Finance Desk-II, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
- 4 AYUSH Budget Section/ Director (P&F)/ Sanction Register.

N. Khatri

Under Secretary to the Government of India
Ministry of AYUSH, GPO Complex
AYUSH Bhawan, B-Block, GPO Complex
INA, New Delhi-23

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

REPUBLIC OF INDIA
APPENDIX - I

GRANT IN AID BILL (FOR USE OF DEPARTMENTAL AUTHORITIES)

DEPARTMENTAL ACCOUNTS - Expenditure is debitable to the Demand No.006 - Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy, 2210 - Medical & Public Health (Major Head), 02200 - Other Systems (Minor Head), 28 - Ayush & Public Health, 280031 - Grant-in-aid - General (Plan) during 2015-16.

Received the sum of Rs. 49,24,000/- (Rs. Forty nine lakhs twenty four thousand only) being the amount sanctioned under the Government of India, Ministry of AYUSH sanction letter No. Z-28014/09/2014-PH dated 05 July, 2015 (copy enclosed) for payment to the grantee institution as mentioned in the letter.

certified that

- i. The grantee institution has submitted bill as per prescribed proforma
- ii. I have no reason to believe that the grantee institution is involved in corrupt practice;
- iii. The amount claimed in this bill has not been drawn earlier;
- iv. The terms and conditions of the grant are acceptable to the grantee institution;
- v. No Utilization Certificate is pending.

T.C.S. for Rs. 49,24,000/- (Rs. Forty nine lakhs twenty four thousand only) may be issued in favour of, "Shri B. M. Kankanwadi Ayurved Mahavidyalaya", Belgaum, Karnataka - 590003. .

(FOR USE OF TREASURY)

PAID Rs
Examined
Treasurer
Treasury Officer
(FOR USE IN ACCOUNTANT GENERAL OFFICE)
ADMITTED RS
OBJECTED RS

AUDITOR

SUPERINTENDENT

GAZETTED OFFICER

R. K. Khatri
R. K. KHATRI
Under Secretary
Ministry of AYUSH, Govt. of India
AYUSH Bhawan, B-Block, GPO Complex
INA, New Delhi-23

ATTESTED

V.A. Kothiwale
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

No. Z. 2801409/2014 PH
Government of India
Ministry of AYUSH
P & F Scheme (PH) Section 4

1	Head of Account	The expenditure is debitabte to the Demand No.006 Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy, 2210- Medical & Public Health (Major Head), 02200 Other Systems (Minor Head), 28 -Ayush & Public Health, 280031-Grant-in-aid - General (Plan) during 2015-2016.
2.	Total allotment in BE 2015-16	Rs. 3,91,00,000/-
3.	Net amount of this bill	Rs. 49,24,000/-
4	Previous expenditure from 1.4.2015	Rs. 44,28,020/-
5	Balance left over after the present bill	Rs. 2,97,47,980/-

R. K. Khatri
R. K. KHATRI
Under Secretary
Ministry of AYUSH, Govt. of India
AYUSH Bhawan, B-Block, GPO Complex
INA, New Delhi-23

ATTESTED

V.A. Kothiwale
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

REQUISITION FORM FOR THE ELECTRONIC TRANSFER OF FUNDS:-

Item	Information
1. Name of the Grantee Institution :-	Principal, Shri B. M, Kankanwadi Ayurveda Mahavidyalaya,
2. Name Of the Bank :-	State Bank of India
3. Full Address of the Bank	Near Arun Theatre, Congress Road, Tilakwadi, Belagavi
4. Account No.	30563401362
5. IFSC Code	SBIN0004160
6. Amount to be Transferred	Rs. 49,24,000(Rupees forty nine lakhs twenty four thousand only)
7. MICR Code	590002009

Signature of the Grant Sanctioning Authority:

R. N. KHATRI
R. N. KHATRI
Under Secretary
Ministry of AYUSH, Govt. of India
AYUSH Bhawan, B-Block, GPO Complex
INA, New Delhi-23

FOR OFFICE USE OF PAO (S) ONLY

Name of the DDO	
Bill No	
D.V. No.	
Cheque No. & Cheque Date	
Cheque Amount	

(SR. ACCOUNTANTS OFFICER)
PAY & ACCOUNTANT OFFICER (SECTT)

ATTESTED

V.A. Kothiwate
Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research
(Deemed to be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Government of India
Ministry of AYUSH

AYUSH BHAWAN,
B-Block, GPO Complex,
INA, New Delhi-110023.
Dated: 12/01/2018

To,
The Pay & Accounts Officer (Secretariat),
Ministry of Health & Family Welfare,
Nirman Bhawan,
New Delhi-110011.

Sub: Release of 2nd installment of Rs. 49,24,000/- (Rupees Forty Nine Lakh Twenty Four Thousand only) of non-recurring grants-in-aid during the financial year 2017-18 (revenue) regarding.

Sir,

In exercise of power delegated under Rule DFPR-1978, I am directed to convey the sanction the President to the payment of Rs. 49,24,000/- (Rupees Forty Nine Lakh Twenty Four Thousand only) to BHASHA Research and Publication Centre as 2nd installment of non-recurring grants-in-aid for research project under PHI Scheme of Ministry of AYUSH during the financial year 2017-18 as detailed below:

Sl. No.	Name of the Organization	AYUSH intervention	Amount to be released	Installment
1	B.M.Kankanwadi Ayurvedic Mahavidyalay, Belgavi, Karnataka	Creating sustainable to address to anemia in school children of Rural Area School under Primary Health Centre, Hudali of Belgaum District, Karnataka through Ayurveda	Rs. 49,24,000/-	2 nd installment

- The grant will be subjected to the terms & condition for grants-in-aid under the scheme for Promotion of AYUSH Intervention in Public Health Initiatives in AYUSH and further subject to the relevant conditions prescribed under General Financial Rules of Govt. of India.
- The grant-in-aid will also be subject to the conditions that no amount or part thereof shall be delivered to any purpose other than the one for which it has been sanctioned.
- It is certified that the Grant-in-aid is being released as 2nd installment in respect of above project to the said B.M.Kankanwadi Ayurvedic Mahavidyalay, Belgavi, Karnataka.
- The Grants-in-aid as per provision of Rule 206 to 245 of General Financial Rules - 2017 will be subjected to the conditions laid down in GFR-2017.
- The accounts of the Grantee institutions/organizations shall be open to inspection by the sanctioning authority and audit both by the CAG of India under the provision of CAG (DPC) Act, 1971 and internal audit wing of the O o CCA of the Ministry, whenever the institutions or organization is called upon to do so.
- It is certified that the amount of grant sanctioned is within the budget provision as accepted in the Budget Estimate for financial year 2017-18. It is also certified that the

been approved by the Ministry of Finance.

ATTESTED

Signature
Dr. P. K. KUNDAN B. SINGH
Under Secretary
Ministry of AYUSH Govt. of India

OS
Dr. V.A. Kottiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed to be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

AYUSH BHAWAN, B-Block, GPO Complex, INA, New Delhi-110023.
AYURVED MANGALAYATA & CONSULTANT UNIT OF KARNATAKA STATE, BELGAVI-590003.
DATE: 22/1/18
1080

... Demand No 005
... AYUSH & Public Health, 20031-Grant-in-Aid General
Revenue during 2017-18.

8. It is non-recurring expenditure and it is the 2nd installment.
9. This sanction issues with the approval of AS & IA vide the Integrated Finance Division Concurrence Dy.No.C-2539 dated 02.01.2018.
10. It is certified that the Grantee organization is not a defaulter in submission of Utilization Certificate.

Yours faithfully,

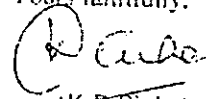

(K.B.Sinha)

Under Secretary to the Govt. of India
... Under Secretary
... भारत सरकार
... Ministry of AYUSH Govt of India
... 110002, New Delhi

Copy to:

1. The Director General of Audit, Central Revenues, I.P. Estates, New Delhi-110003.
2. B.M.Kankanwadi Ayurvedic Mahavidyalay, Belgavi, Karnataka 590003.
3. Finance Desk-II, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
4. Budget Section/Director (P&E)/Sanction Register M/O AYUSH.
5. Cash section, M/O AYUSH.

Yours faithfully,


(K.B.Sinha)

Under Secretary to the Govt. of India

कुन्दन भा. सिन्हा/KUNDAN B. SINHA
... Under Secretary
... भारत सरकार
... Ministry of AYUSH Govt of India
... AYUSH Bhawan B-Block GPO Complex INA New Delhi-22

ATTESTED


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka.

[See Rules 47, 48, 49 & 50]

BILL NO. CP00000 GRANTS-IN-AID- BILL / AYUSH/ 2017-18 DATED 2018
(S.B. No...../Grants/2210-02-02200-280031 (R) 2017-18 dated 2018

MINISTRY OF AYUSH

DDO Code:

Head of Account:

The Expenditure is debitable to Demand No 005 – Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homoeopathy.

2210 – Medical & Public Health (Major Head).

02200- Other systems (Minor Head). 28 – Ayush & Public Health. 280031- Grant-in-aid General (Revenue) during 2017-18

Received the sum of Rs. 49,24,000/-

(Rupees Forty Nine Lakh Twenty Four Thousand only)

Being the Second installment of non-recurring grant-in-aid to B. M. Kankanwadi Ayurvedic Mahavidyalay under the Central Sector grant-in-Aid Scheme for Promotion of AYUSH, Intervention in Public Health Initiatives during 2017- 2018 (Revenue)

Sanctioned by public Health Initiatives (PHI) Scheme Section of the Ministry of AYUSH in its sanction letter No - Z- 28014/09/2014-PHI dated 12-01-18 (copy enclosed)

Countersigned for Rs. 49,24,000/- (Rupees Forty Nine Lakh Twenty Four Thousand only)	Budget Estimate for 2017-18	Rs. 5,66,00,000/-
	Exp dr. Including this bill	Rs.2,43,77,755 /-
Funds may be transferred through ECS to:		
	Balance Rs.	Rs.3,22,22,245/-

Shri B.M. Kankanwadi Ayurvedic
Dated: Mahavidyalay. (Belgavi)

DDO
Signature
Designation of DDO

FOR USE IN PAY AND ACCOUNT OFFICE

Passed for payment of Rs. (Rupees

Payment by
Dated:
Cheque No.

Received
12/1/18

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- HomeWiseContractDetails
- Reports
- Users
- Plans
- Agency
- Sanctions
- Sanction Custom Fields
- Printing Templates
- Sanction Templates
- Employee Info. System
- Users
- Schemes
- Agency
- Grant Allocation
- Sanction/Track Issue
- Sanction Certificate
- UC

Controller: 317454 Tr. and P.M. ...
Sanction Number: 20801405/2014 PH
Sanction Type: Transfer (DDO Bal.)
IFD Number: C-2539
Plan Scheme: 0132-AYUSH AND PUBLIC HEALTH
DDO: 220473-DEPTT. OF ISM&H RESEARCH BUILDING, NEW DELHI
Sanction Status: Approved
Sanction Date: 12/01/2018
Sanction Amount: 4924000
IFD Date: 02/01/2018
PAO: 020855-PAO/Sectt. of Health & Family Welfare, New Delhi
Remarks: Approved
Created By: schatterjee
Created On: 03/01/2018 10:32 56 AM
Modified By: schatterjee
Modified On: 12/01/2018 10:21 29 AM

Account Details:

Grant	Department (For UT Grants Only)	Function Head	Object Head	Category	Amount	External PAD	Available Budget
005 - M/o of Ayurveda, Yoga & Naturo, Unani, Siddha & Homeo		2210022002800 - AYUSH AND PUBLIC HEALTH	31 - GRANTS-IN-AID GENERAL	5 - VOTED	4924000		32222245


Agency Details:

Sr.No	Agency Name	City	District	State	Country	Gross Amount	Deduction Amount	Net Amount	Payee Remarks
1	Shri B.M. Kankarwad Ayurved Mahavidyalaya, Belgaum	Belgaum	BELGAUM	KARNATAKA	INDIA	4,924,000	0	4,924,000	Approved

Sanction Approved Successfully But SMS has not been sent due to network issue.

[Payee Details](#) [Print Sanction Order](#) [Back](#)

Jinka
 1 श्री. विजयकुन्दन एस. सिने
 १२ सचिव/Under Secretary
 मुख्य मंत्रालय, भारत सरकार
 Ministry of AYUSH Govt. of India
 नया दिल्ली-110002
 14, New Delhi-23

ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

(UNDER RUPEES SIXTY LAKH ONLY)

APPENDIX - I

GRANT-IN-AID BILL (FOR USE OF DEPARTMENTAL AUTHORITIES)

The HEAD OF ACCOUNT - expenditure is debitable to the Demand No.005 - Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy, 2210- Medical & Public Health (Major Head), 02200 -Other Systems (Minor Head), 28 -AYUSH & Public Health, 280031-Grants-in-aid- General (Plan) during 2017-18.

Received the sum of Rs. 49,24,000/- (Rupees Forty Nine Lakh Twenty Four Thousand only) being the amount sanctioned under the Government of India, Ministry of AYUSH sanction letter No. Z- 28014/09 /2014 -PHI dated 12/02/16. (Copy enclosed) for payment to the grantee institution as mentioned in the letter.

Certified that:

- i. The grantee institution has been furnished the Bond, Undertaking and certificate being a State Government organization.
 - ii. I have no reason to believe that the grantee institution is involved in corrupt practice.
 - iii. The amount claimed in this bill has not been drawn earlier.
- The terms and conditions of the grant are acceptable to the grantee institution:
No Utilization Certificate is pending.

Ex.C.S. for Rs. 49,24,000/- (Rupees Forty Nine Lakh Twenty Four Thousand only) may be issued in favor of. "B.M.Kankanwadi Ayurvedic Mahavidyalay, Belgavi, Karnataka".

(FOR USE OF TREASURY)

Pay Rs.

Examine

Treasury Accountant

Treasury Officer

(FOR USE IN ACCOUNTANT GENERAL OFFICE)

ADMITTED RS.

OBJECTED RS.

AUDITOR

SUPERINTENDENT

GAZETTED OFFICER


ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2017-18
Government of India
Ministry of AYUSH
[PH Scheme (PH) Section]

1	Head of Account.	The expenditure is debitable to the Demand No.005 - Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy. 2210- Medical & Public Health (Major Head). 02200 -Other Systems (Minor Head). 28 -AYUSH & Public Health. 280031-Grants-in-aid - General (Revenue) during 2017-18.
2.	Total allotment in BE 2017-18	Rs. 5,66,00,000/-
3.	Net amount of this bill	Rs. 49,24,000/-
4.	Previous expenditure	Rs. 1,94,53,755/-
5.	Balance left over after the present bill	Rs. 3,22,22,245/-


कुन्दन भू सिन्हा/KUNDAN B SINHA
अधर सचिव/Under Secretary
आयुष मंत्रालय, भारत सरकार
Ministry of AYUSH Govt of India
अनु. 25A, ई-ब्लॉक, गणतंत्र भवन, अरुणोदय भवन, नई दिल्ली-23
AYUSH Bhawan B Block - GPU Complex INA New Delhi-23

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

No. Z-28014/09/2011-PIII

REQUISITION FORM FOR THE ELECTRONIC TRANSFER OF FUNDS

Item	Information
1. Name of the Grantee Institution	B.M.Kankawadi Ayurvedic Mahavidyalay , Belgavi, Karnataka
2. Name Of the Bank	State Bank of India,Urmi Branch
3.Full Address of the Bank	Near Arun Theatre , Congress Road , Tilakwadi, Belgavi
4. Account No.	30563401362
5. IFSC Code	SBIN0004160
6. Amount to be Transferred	Rs. 49,24,000/- (Rupees Forty Nine Lakh Twenty Four Thousand only)
7. MICR Code	590002009

Signature of the Grant Sanctioning Authority/other Competent Authority:

PRADEEP KUMAR B SINHA
Joint Secretary, Ministry of Health & Family Welfare
GOVT OF INDIA
Ministry of AYUSH Govt of India
New Delhi-110002

FOR OFFICE USE OF PAO (S) ONLY

Name of the DDO	
Bill No	
D.V. No.	
Cheque No. & Cheque Date	
Cheque Amount	

(SR. ACCOUNTANTS OFFICER)
PAY & ACCOUNTANT OFFICER (SECTT.)

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

CRF3

File No. Z-15014 15 2015- PHH

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homoeopathy (AYUSH)

AYUSH BHAWAN, B Block, GPO Complex,

INA, Delhi - 110023

Dated 27th October, 2017

OFFICE MEMORANDUM

Subject: Minutes of the Meeting of Project Appraisal Committee (PAC) for the Central-Sector Grant-in-aid Scheme for Promotion of AYUSH Intervention in Public Health Initiatives (PHI) held on 12 October, 2017 - regarding.

Please find enclosed herewith the minutes of the meeting of the Project Appraisal Committee (PAC) held on 12.10.2017 under the Chairmanship of Joint Secretary (PKP) AYUSH to consider the proposals received under the Central Sector Grants-in-aid Scheme for Promotion of AYUSH Intervention in Public Health Initiatives (PHI) for perusal and necessary action.

Dr. S.R.K. Vidyarthi
(Director)

To:

All the participants and members of PAC (as per list at Annexure)

Copy to:-

1. Sr. PPS to Secretary
2. PS to JS (PKP)
3. PS to Adv. (Ay.) Dr. MN
4. PS to Adv. (Ay.) Dr. Katoch

OS
CRH
RCB
PIAR (Ay.)
MRC
Co-ordinator

→ file
→ collaborate
→ projects

ATTESTED

Dr. V.A. Kothiwale

OFFICIAL STAMP
KLE Academy of Higher Education and Research
(Deemed-to-be University u/s 3 of the UCC Act 1956)
Belagavi-590 010, Karnataka

201

1. Name of the organization: - Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Belgavi, Karnataka.

The title of proposal "Prevention of Diseases and Promotion of Quality of Life, by application of Principles of Ayurveda". For release of Rs.49,24,000/- (40%) for 2nd installment Objective of proposal is to bring down the incidence and prevalence of vector borne diseases- Chikungunya, Dengue and Malaria. To bring down the incidence and prevalence of non-communicable diseases like Hypertension, Diabetes etc. reduce the cost of health care. To increase the quality of life of villagers in Belgavi dist. under PHI Scheme.

PAC observed that utilization certificate of first installment has been accepted and monitoring committee has given a satisfactory report. PAC accepted the suggestion of monitoring committee, that achieve all the deliverables of the project to an optimum extent. continuous health monitoring for identifying health problems through checkup, camps, persistent anemia assessment and management, enhance capacity building measures for health improvement, reinforce positive health attitude in students, to create better awareness among villagers of health, continuation of project for approved three years is needed. To include promotion of Swachha Bharat Programme in the project from 2nd year onwards.

Recommendation of PAC: After detailed deliberation, PAC decided to recommend this proposal to PSC for sanction of 2nd installment of Rs.49,24,000/-.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

MRC/2016/01/301



INSTITUTIONAL ETHICS COMMITTEE
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur. Belgaum

**Communication of decision of the institutional ethics
committee (IEC)**

Protocol No.: BMK/15/BSP/01

Protocol Title: "Creating sustainable solutions to address Anemia in school children of Rural Area (Schools under Primary Health Center, Hudali of Belgaum District, Karnataka) through Ayurveda"
Principal Investigator/ Co-investigator: Dr. B. S. Prasad Dr. Sandeep Sagare
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya & KLE Ayurved Hospital, Shahapur. Belgaum
<input checked="" type="checkbox"/> New Review <input type="checkbox"/> Revised Review <input type="checkbox"/> Expedited Review
Date of Review(DD/MM/YY): 30/10/2015 Date of previous review, if revised application: Name of the Reviewers who attended the meeting: Dr Subarna Roy, Dr Harsha Hegade, Dr Semeer naik, Dr Rajashree Kamat, Mr Sudir Kulkarni, Mrs Sarita Shirodkar, Shri Neminath Kune, Dr. Basavraj R Tubaki
Decision of the Ethics Committee: Recommended <input checked="" type="checkbox"/> Recommended with suggestions <input type="checkbox"/> Revision <input type="checkbox"/> Rejected <input type="checkbox"/>

Page 1 of 2

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka


Suggestions/ Clarifications / Reasons/ Remarks:

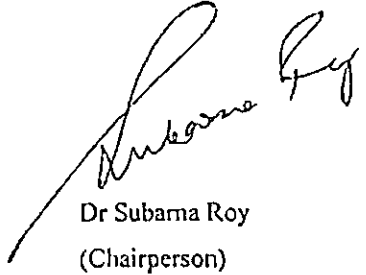
Following are the suggestions/clarifications of the EC- NIL

Recommended for a period of : Three year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse


Dr. Basavaraj R Tubaki
(Member Secretary)


Dr Subarna Roy
(Chairperson)

Page 2 of 2

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

WUE / BMK / MRC / SJF / 15

20/11/18



Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/14/BSP/02

Protocol Title: "Creating sustainable solutions to address Anemia in school children of Rural Area (Schools under Primary Health Center, Hudali of Belgaum District, Karnataka) through Ayurveda"		
Principal Investigators/Co-investigators: Dr. B S Prasad Dr. Sandeep Sagare		
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya & KLE Ayurved Hospital, Shahapur, Belagavi		
<input type="checkbox"/> Review	<input checked="" type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review
Date of Review (DD/MM/YY): 24/11/2018		
Date of previous review, if revised application: 30/10/2015		
Name of the Reviewers who attended the meeting: Dr. Supriya Bhalerao, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Dr. Aziz, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki		
Decision of the the Ethics Committee: Recommended <input checked="" type="checkbox"/> Recommended with suggestions <input type="checkbox"/> Revision <input type="checkbox"/> Rejected <input type="checkbox"/>		
Suggestions/ Clarifications / Reasons/ Remarks: NIL		

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 1 of 2

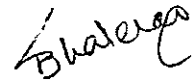
Recommended for a period of :Three Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse



Dr. Basavaraj R Tubaki
(Member Secretary)



Dr. Supriya Bhalerao
(Chairperson)

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 2 of 2



Dr. A Mukhopadhyay
Adviser/ Scientist 'G'
SERC Division
Email: tsd@nic.in
Phone: 26590445
26602193 (direct)
Fax: 011-26602193

सं. १५६७
विज्ञान आणु प्रौद्योगिकी मंत्रालय
विज्ञान आणु प्रौद्योगिकी विभाग
टेक्नोलॉजी भवन नया मेहरौली मार्ग नई दिल्ली - 110016

GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
Department of Science & Technology
Technology Bhawan New Mehrauli Road New Delhi-110016

SR/FST/ College - 103/2012

15th November 2012

Subject: Your Proposal under "FIST Program - 2012" [289]

Dear Sir,

This is in connection with the aforesaid proposal submitted by your Department/ Centre for support under the FIST Program of DST. We are happy to inform you that the aforesaid proposal has been identified for support in Level-0 category by the DST based on the recommendations of the FIST Advisory Board (FISTAB). The details of the recommendations for 5 years duration of the project are given below:

To strengthen Teaching and Research Facilities in all Science departments of the College.
E = Rs 32 lakh (Items to be identified for Teaching Facilities by the College) and Rs 50 lakh for items to be identified for Research Facilities.
NW = Rs 7 lakh (for Setting up Computer Lab)
Books = Rs 3 lakh
Renovation of Lab = Rs 5 lakh (for making e-Learning Room)

It may be noted that the allocations indicated now above with respect to any Equipment or any other budget heads are the upper limit of the budget as they are purely based on recommendations and also tentative. However, Department shall now finally firm-up specifications/ configurations of each Equipment, Computational & Networking facility in Computer Lab, Infrastructure Facility as recommended above for acquiring by the Department/ Centre/ School and actual cost of this project shall be firm up based on these inputs from you. The support for the 'Maintenance' will be provided as per norms under FIST Program. The type of equipment and its specifications/ configurations finalized now by the Department/Centre/ School would not be possible to change during the course of implementation of the said project. For enabling us to process the case further, including the release of 1st instalment of grant now, you are requested to please submit the following documents latest by before 17th December 2012 (Monday):

- 1) One each Budgetary Quotation from Equipment supplier (all-inclusive i.e. Custom Duty, Bank & other Charges) for all Equipment recommended for support. Please ensure that the budgetary cost is not an inflated one with respect to its specifications given. In case, Equipment list "to be identified & prioritized", please submit quotations of the identified & prioritized Equipment only.
- 2) Details plans for implementation of the 'Networking and Computational Facilities' (NW) under the support as per guidelines mentioned in the *Terms and Conditions* of DST-FIST Program available at the Website: www.fist-dst.org. Please download 'Terms & Conditions' and submit the same on completion of all formalities along with above-said documents to DST.
- 3) Details & their cost estimates of Items/ activities recommended & proposed under 'Infrastructure Facility' which includes the list of Books, etc.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Ch
23/11/12

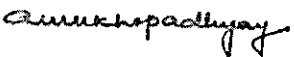
- 4) For implementation of the project, the Department/School/Centre/College shall constitute an 'Project Implementation Group' who shall be responsible & accountable for its implementation during the project duration of 5 years. The composition of the 'Project Implementation Group' shall be informed to DST by the Department/School/ Centre.
- 5) The respective Department/ School/ Centre/College shall open an only Saving Bank Accounts to handle the project grants. However, the concerned Department/Centre or College shall need to forward a photocopy of a Blank Cheque only for their Institute/ University/College Bank Account which is maintained & operated by the Registrar (for University) or Director (for Institute) or Comptroller (for Agricultural University) or Principal (for College) to facilitate the transfer of grants through ECS Transfer System. The Department/Centre or College shall also be requested to ensure the registration in Central Plan Scheme Monitoring System (CPSMS) [www.cga.nic.in] for SERC (1009) head of A/c and attach the Registration Certificate of their University/Institute/College along with other documents.

The Department/ Centre/ School who have already enjoyed support earlier under FIST Program and recommended for Repeat Support now, shall need to complete all formalities i.e. submission of Project Completion Report, Audited Financial Statements, refund of unspent funds etc. for the previously supported project under DST-FIST Program. Processing towards releasing the grants to such Department/ School/ Centre would not be possible to initiate without completion of all formalities for the previous project. Blank Format towards closure of previous project is also available at the Website: www.fist-dst.org.

Departments/ Centres/ Schools/ College are also requested for sending all documents at one stage instead of sending in parts by Post only. Please avoid of sending these documents by Email as well as at the last moment. Incomplete documents submitted by any Department/ Centre/ School/ College would be unable to process for releasing grants and the matter would be kept pending maximum for six months, beyond which recommendations for the Department/Centre/School/ College deemed to be forfeited automatically for considering support under DST-FIST Program.

We look forward for kind cooperation from you in this regard and if any clarifications are needed, please feel free to contact us. Please submit the following documents before 17th December 2012 (Monday). All documents will be required to send by Post. Documents may not be sent by E-mail for releasing fund.

With best regards.


(A. Mukhopadhyay)

To

Principal,
Shri B.M. Kankanowadi Ayurved Mahavidyalaya,
Shahapur,
Belgaum-590003,
Karnataka

[Note: E – Equipment, NW – Networking & Computational Facility, IF – Infrastructure facility, M – Maintenance]

ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

DEPARTMENT OF SCIENCE & TECHNOLOGY

TERMS AND CONDITIONS
FOR
“ Fund for Improvement of S&T Infrastructure in Universities and Higher Educational Institutions (FIST) ” GRANT.

In recent years, scientific community has expressed great concern about the lack of infrastructure facilities for imparting good quality of higher education and conducting research in emerging fields of science and engineering. Several efforts have been made in past to strengthen research as well as teaching in carefully identified areas and university departments. These departments are now in a stage for further strengthening of their infrastructure to enhance their visibility both nationally and internationally. It has also become necessary to extend such infrastructure support to other higher technical and medical educational institutions.

Keeping all these factors in mind, a new scheme entitled “Fund for Improvement of S&T Infrastructure in Universities and Higher Educational Institutions – (FIST)” has been initiated.

The Terms and Conditions:

- The grant being released under the scheme is for strengthening infrastructure of the identified department for teaching and research and shall be spent exclusively for this purpose. The Head or its nominee (to be decided by the Department/ Institute/ University) of the identified Department/ Centre shall be the “Program Coordinator for the DST-FIST”.
- There should not be any deviation from the Budget Heads as approved by DST. In case, if it is very necessary, a request can be made to the DST for consideration.
- The grants-in-aid for “**Networking and Computational Facilities**” being released under the scheme should be utilized for creating a “**Central Computer Lab**” in the identified Department/ Centre for teaching and research with the following guidelines / norms:
 - a. Internet Connectivity (to be provided by Institution)
 - b. Server + Hub + Modem
 - c. Several PCs or Net-Computers proportional to number of students enrolled
 - d. UPS
 - e. Access for Students and Faculties in the Department

The Institution should also make sure that this grant is not meant for just providing PCs to each of the Faculty members in the Department.

- The grants-in-aid under “FIST” is to provide infra-structural facilities for research and teaching in the department. Therefore, ***no provision of Overhead Charges*** is admissible. **Please note that the scheme does not allow any provision for building/construction and recruitment of staff** etc.
- All the assets acquired from the grant will be the property of the Government of India and should not, without the prior sanction of the Department, be disposed off or encumbered or utilized for purposes other than those for which the grant has been sanctioned.

... Contd. 2

ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956
Belagavi-590 010, Karnataka

- All efforts should be made to procure the equipment and other items at the earliest to avoid cost escalation due to foreign exchange fluctuation and should abide all procedures laid out by the grantee institution. In case it is found that the Department is not able to use the funds within two years of its release, the Department of Science & Technology shall have the right to withdraw the project from the Department/ University.
- The Institute will furnish to Department of Science & Technology, Utilization Certificate and an audited Statement of Accounts (in DST format) pertaining to the grant (along with Progress Report) within three months following the end of each financial year.
- After receiving the grant by the Department/ Centre, Department of Science & Technology will review the technical & financial progress including utilization of the grant on an annual basis with an appropriate mechanism. The Department reserves the right to terminate the support at any stage if it is convinced that the grant has not been properly utilized or appropriate progress is not being made.
- A register of the permanent/semi-permanent assets acquired wholly or mainly out of this grant should be maintained in the prescribed form and a copy thereof furnished to this Department. Such register of assets and the accounts maintained shall be available or open to scrutiny by Audit.
- Any unspent amount sanctioned would be surrendered to the Government as a Demand Draft in favour of Drawing & Disbursing Officer, Department of Science & Technology, New Delhi. Any carry forward of funds to the next financial year may be considered only with the specific approval of the Department.
- The Comptroller and Auditor General of India, at his discretion, shall have the right to access to the book accounts for this support. It is found expedient to keep a part or whole of the grant in a bank account earning interest. The interest thus earned should be reflected appropriately in the Financial Statement of each year submitted to the Department of Science & Technology. The interest thus earned will be adjusted against further installment of the grant.
- In order to give visibility to the identified department, the department may be called as "DST-FIST Sponsored Department". This may be suitably displayed.

Signed by

Signed by

Head of the Department/ Centre

Head of the Institute

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

NSRF FIST College 2013-14
GOVERNMENT OF K.L. -
MINISTER OF SCIENCE & TECHNOLOGY
DEPARTMENT OF SCIENCE & TECHNOLOGY
NSRF & FIST COLLEGE

Technology, Bhekar
New Marra, Post
New Den - 590003

21st November 2013

ORDER

1. All Funds assistance in payment to the KLE University's Shri B.M. Kankarawadi Ayurved Mahavidyalaya, Belgaum-590003 (Karnataka), on FIST Program

2. Sanction of the Present is hereby accorded to the implementation of the aforesaid project at a total cost of Rs. 95,00,000 - (Rupees Ninety five lakh only) for 5 years at the KLE University's Shri B.M. Kankarawadi Ayurved Mahavidyalaya, Belgaum-590003 (Karnataka). The details of this are given below.

To strengthen the teaching and research facilities in all Science Departments of the College

Capital Assets-Rs 92.00 L:

E-Rs 77.00L - A) Teaching Facility: Rs 27.00L for (i) Simulators- 16 items, (ii) Microscope-4 items and (iii) Operational Theatre-5 items are accepted (as per list) to support, however Smart Class Room and Plasma TV are beyond the scope to support in Equipments and B) Research Facility: Rs. 50.00L for Sr. No. 1 to 4 (as per list) to support, however Sr. no. 5 to 11 are beyond the scope to support.

F-Rs. 8.0L [Renovation of labs for setting up a e-Learning Class Room-Rs 5.00L & Books-Rs.3.00L]

Networking-Rs.7.0L [To set up Computer Lab]

General Components-Rs.3.00L:

M-Rs.3.00L

Total: Rs. 95.00 Lakh

3. The sanction of the Present is also accorded to the release of Rs.84,50,000.- (Rupees Eighty four lakh and fifty thousand only) to the Principal, KLE University's Shri B.M. Kankarawadi Ayurved Mahavidyalaya, Belgaum-590003, (Karnataka) under FIST Program as a 1st instalment of the grant in 2013-2014 under 'creation of capital assets' head for the maximum cost of the aforesaid Equipment including (9.4%) Custom Duty & other duties. The break-up of the grant released now would be "Equipment": Rs.77.00 lakh for procurement of the equipments mentioned above [Equipments of Foreign Origin to be acquired on FE Terms only], "Infrastructure facility": Rs.0.50 lakh for acquiring Books & "Networking and Computational facilities": Rs.7.00 lakh. Under the "Networking & Computational facilities" the proposed lab will have 10 nos. Desktops, 1 Sever, 1 UPS and Networking accessories.

4. The Department/College will appropriately limit the expenditure within the sanctioned amount in case of any expected excess expenditure. The College is requested to utilize the released funds in first one year.

5. The KLE University's Shri B.M. Kankarawadi Ayurved Mahavidyalaya, Belgaum-590003, Karnataka shall implement the aforesaid project with the 'Terms and Conditions' already agreed to by the College. Further as per Rule 211 of revised GFRs the accounts of this Project Grants at Grantee Organization shall be made available for inspection by the sanctioning authority/audit wherever the Organization is called upon to do so.

6. There is no Pending SE/UC on this project. This is the first release of this project under FIST Program which has been initiated in this financial year so no previous UC is attached with this sanction order.

7. The College will furnish to the DST, Utilization Certificate and an audited Statement of Expenditure pertaining to the grant immediately after the end of each financial year.

Dr. V. K. Wale
Registrar

68

UNIVERSITY COLLEGE-590003,
GOVERNMENT OF KARNATAKA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF SCIENCE & TECHNOLOGY
INSPIRE & FIST DIVISION

Technology Branch
'New Marra' Road
New Delhi-110016

21 November 2013

ORDER

Subject: Financial assistance (1st instalment) to the KLE University's Sri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-590003, (Karnataka) on FIST Program

Sanction of the President is hereby accorded to the implementation of the aforesaid project at a total cost of Rs. 95,00,000/- (Rupees Ninety five lakh only) for 5 years at the KLE University's Sri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-590003 (Karnataka). The details of this are given below

To strengthen the teaching and research facilities in all Science Departments of the College

Capital Assets-Rs.92.00L:

E-Rs.77.00L - A) Teaching Facility : Rs.27.00L for (i) Simulators- 16 items, ii) Microscope-4 items and iii) Operational Theatre-6 items are accepted (as per list) to support, however Smart Class Room and Plasma TV are beyond the scope to support in Equipments and B) Research Facility: Rs. 50.00L for Sr. No. 1 to 4 (as per list) to support, however Sr. no. 5 to 11 are beyond the scope to support.

IF-Rs. 8.0L [Renovation of labs for setting up a e-Learning Class Room-Rs.5.00L & Books-Rs.3.00L]
Networking-Rs.7.0L [To set up Computer Lab]

General Components-Rs.3.00L:

M- Rs.3.00L

Total : Rs.95.00 Lakh

2. The sanction of the President is also accorded to the release of Rs.84,50,000/- (Rupees Eighty four lakh and fifty thousand only) to the Principal, KLE University's Sri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-590003, (Karnataka) under FIST Program as a 1st instalment of the grant in 2013-2014 under 'creation of capital assets' head for the maximum cost of the aforesaid Equipment including (9.4%) Custom Duty & other duties. The break-up of the grant released now would be "Equipment": Rs.77.00 lakh for procurement of the equipments mentioned above [Equipments of Foreign Origin to be acquired on FE Terms only], "Infrastructure facility": Rs.0.50 lakh for acquiring Books & "Networking and Computational facilities": Rs.7.00 lakh. Under the "Networking & Computational facilities" the proposed lab will have 10 nos. Desktops, 1 Server, 1 UPS and Networking accessories.

3. The Department/College will appropriately limit the expenditure within the sanctioned amount in case of any expected excess expenditure. The College is requested to utilize the released funds in first one year

4. The KLE University's Sri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-590003 (Karnataka) shall implement the aforesaid project with the 'Terms and Conditions' already agreed to by the College. Further, as per Rule 211 of revised GFRs the accounts of this Project Grants at Grantee Organization shall be made available for inspection by the sanctioning authority/ audit where ever the Organization is called upon to do so.

5. There is no Pending SE/UC on this project. This is the first release of this project under FIST Program, which has been initiated, in this financial year so no previous UC is attached with this sanction order.

6. The College will furnish to the DST, Utilization Certificate and an audited Statement of Expenditure pertaining to the grant immediately after the end of each financial year.

(Comb-2)

Dr. V. K. Kulkarni
Registrar

The amount of Rs. 84,50,000/- (Rupees Eighty four lakh and fifty thousand only) will be disbursed to the Principal, KLE University's Shri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-590003, (Karnataka) in its A/c No. 05042010103806, IFSC Code: SYNB0000504 with Syndicate Bank, Belgaum Nehru Nagar.

- 1 - General (Sr. Major Head)
- 2 - Department of Science & Technology
- 3 - 425 - Other Scientific Research (Major Head)
- 4 - Other (Sr. Major Head)
- 5 - 200 - Assistance to other Scientific Bodies (Minor Head)
- 6 - 25 - Research & Development Support
- 7 - 25 01 - Grants in aid for R&D Support
- 8 - 25 01 35 - Grants for creation of capital assets for the year 2013-2014 (Plan)

The above release is made under R&D Scheme

9. The amount of Rs.84,50,000.- (Rupees Eighty four lakh and fifty thousand only) will be disbursed to the Principal, KLE University's Shri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-590003, (Karnataka) in its A/c No. 05042010103806, IFSC Code: SYNB0000504 with Syndicate Bank, Belgaum Nehru Nagar.

10. The sanction issues under the powers delegated to the Ministries and with the concurrence of the Integrated Finance Division, Department of Science & Technology vide their Dy.No. 15317 /IFD/2013-2014 dated. 20.11.2013.

11. The sanction order is entered vide FIST No. 189 dated 21.11.2013 in the register of grants

(Signature)
A Bhattacharyya
Scientist 'D'
Email: a.bhattacharyya@nic.in

Copy forwarded for information and necessary action to.

1. Pay & Accounts Officer, Department of Science & Technology, New Delhi - 110 016.
2. Cash Section (with two spare copies).
3. Principal, KLE University's Shri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-590003, (Karnataka).
(Pl. Note the New Project No.) (In case the amount sanctioned for disbursement under this sanction is not received by the P.I within 15 days from the date of issue of the sanction, the PI may intimate the fact with details of the IFD Diary No. & Date to the Joint Secretary and Financial Adviser at the e-mail address fin.adv.dst.dbt@gmail.com for looking into the matter and resolving it).
4. Office of the Director & Audit, Scientific Department, AGCR Bldg. 3rd Floor, IP Estate, New Delhi -110002.
5. Office of Accountant General, Karnataka, Bangalore.
6. Head, INSPIRE & FIST, DST New Delhi.
7. FIST-Secretariat.
8. CoA / IFD, DST, New Delhi.
9. Sanction Folder.

(Signature)
(A. Bhattacharyya)
Scientist 'D'
Email: a.bhattacharyya@nic.in

ATTESTED

*De G...
&
...
...*

(Signature)
Registrar
KLE University's Shri B.M. Kankanawadi Ayurved Mahavidyalaya
(Deemed to be University) DS 3 of the UGC
Belagavi-590 010, Karnataka

The grant is being released subject to the Terms & Conditions of the Program being
... KLE University's Shri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum
(Karnataka). The College University/Institute will maintain separate audited accounts and
would keep a bill of the grant in a bank account earning interest, the interest earned should be
reported to the DST. The interest thus earned will be treated as a credit to the Institute to be
adjusted towards further installment of the grant.

8. The expenditure involved is to be debited to
- Demand No. 85 - Department of Science & Technology,
 - 3425 - Other Scientific Research (Major Head)
 - 60 - Others (Sub-Major Head),
 - 60 200 - Assistance to other Scientific Bodies (Minor Head)
 - 25 - Research & Development Support
 - 25.01 - Grants-in-aid for R&D Support
 - 25 01.35 - Grants for creation of capital assets for the year 2013-2014 (Plan).

The above release is made under 'R&D' Scheme

9. The amount of Rs.84,50,000/- (Rupees Eighty four lakh and fifty thousand only) will
be disbursed to the Principal, KLE University's Shri B.M. Kankanawadi Ayurved
Mahavidyalaya, Belgaum-590003, (Karnataka) in its A/c No. 05042010103806, IFSC Code:
SYNB0000504 with Syndicate Bank, Belgaum Nehru Nagar.

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11. The sanction order is entered vide FIST No. 189 dated 21.11.2013 in the register of
grants.

(A. Bhattacharyya)
A. Bhattacharyya
Scientist 'D'

Email: a.bhattacharyya@nic.in

Copy forwarded for information and necessary action to:

1. Pay & Accounts Officer, Department of Science & Technology, New Delhi - 110 016
2. Cash Section (with two spare copies).
3. Principal, KLE University's Shri B.M. Kankanawadi Ayurved Mahavidyalaya, Belgaum-
590003, (Karnataka).
(Pl. Note the New Project No.) (In case the amount sanctioned for disbursement under this
sanction is not received by the P.I within 15 days from the date of issue of the sanction, the
P.I may intimate the fact with details of the IFD Diary No. & Date to the Joint Secretary and
Financial Adviser at the e-mail address fin.adv.dst.dbt@gmail.com for looking into the
matter and resolving it).
4. Office of the Director & Audit, Scientific Department, AGCR Bldg., 3rd Floor, IP Estate,
New Delhi -110002.
5. Office of Accountant General, Karnataka, Bangalore.
6. Head, INSPIRE & FIST, DST New Delhi.
7. FIST-Secretariat.
8. CoA / IFD, DST, New Delhi.
9. Sanction Folder.

(A. Bhattacharyya)
(A. Bhattacharyya)
Scientist 'D'

Email: a.bhattacharyya@nic.in

ATTESTED

tel: 265688960, 26588895

GRAM : SCIENTIFIC

FAX : 011-6868662

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, POST BOX NO. 4911

NEW DELHI – 110029

File No. 5/3/3/317/2016-ITR
Dated:17.11.2016

The Director
Regional Medical Research Centre (ICMR)
Nehru Nagar
Belgaum-590 010
Karnataka

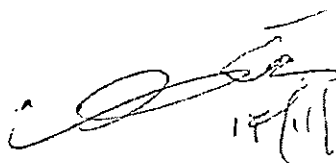
Subject: Sanction of Budget allotment for the ICMR NTF Project entitled, "Preclinical evaluation of safety and efficacy of the decoction of the plant RMRC-BM IP_156 for anti-diabetic activity and characterization of active compound (s)" under Dr.R.K.Joshi,Belgaum

Sir,

The Director General of Rs. 58.88,880/- for a duration of two year i.e. from 1.12.2016 to 30.11.2018 (details in Annexure-I.) The grant-in-aid will be given subject to the following conditions.

The payment of the grant will be made in two installment in the name of Head of the Institute through RTGS BANK ACCOUNT NUMBER: 0505201010915, MICR code of bank 590015002 (A copy of Mandate Form & cancelled cheque are enclosed).

1. The first installment of the grant will be paid generally as soon as report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent installment of the grant should be placed with the Council in advance.
2. The staff appointed on the project should be paid as indicated in the attached budget statement.
3. The approved duration of the research scheme is two years . The annual extension will be given after review of the work done on the research scheme during the previous year.
4. Five copies of the annual progress report of work done be submitted to the Council every year after completion of ten months of the project. Failure to submit the report in time may lead to termination of the project.


17/11/16

ATTESTED

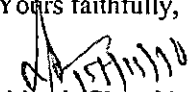


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

5. The Institute will maintain a separate account of the receipts and the expenditure incurred on the research scheme and will furnish an utilization certificate and an audited statement of the account pertaining to the grant.
6. The other terms and conditions are indicated in Annexure-1.

The receipt of this letter may please be acknowledged.

Yours faithfully,

(Subhash Chand)
Admn. Officer
for Director General

Copy together with a copy of the budget statement forwarded for information to:

1. Dr. R.K.Joshi Scientist 'C' Regional Medical Research Centre (ICMR)
Nehru Nagar Belgaum-590 010 Karnataka.
2. Copy together with two copies of the budget statement forwarded to **Accounts Section-V**, ICMR for information and necessary action. The expenditure on the account may be met from the provision made for **Division of ITR for Ad-hoc project** on grant-in-aid basis in the budget of the Council for the financial year 2016-17.
3. Copy together with two copies of the budget statement forwarded to budget section (**Finance**) ICMR for completion of the Council's budget.
4. IRIS cell, ICMR, ID.No. 2014-26050 dated 22.1.2015
RFC No. ITR/Ad-hoc/2/2016-17 dt.3.11.2016

for Director General

ATTESTED


Dr. V.A.Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

KLE/BMK/MIR/9/2/18



INSTITUTIONAL ETHICS COMMITTEE
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: **BMK/17/BSP/05**

Protocol Title: **Evaluation of Add on Efficacy & Safety of An Ayurvedic Formulation In the Management of Dengue Fever & Prevention of Its Complications – A Double Blind Clinical Study**

Principal Investigators/Co-investigators: **Dr. B Sreenivasa Prasad
Dr. S. L. Hoti, , Dr. V A Kothiwale, Dr. M V Jali, Dr. Rekha Patil, Dr. Banappa S. Unger,
Dr. Sukumar N Nandigoudar**

Name & Address of Institution:

**KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital,
Shahapur, Belagavi**

New Review

Revised Review

Expedited Review

Date of Review (DD/MM/YY): 20.03.2018

Date of previous review, if revised application: 25.03.2017

Name of the Reviewers who attended the meeting:

**Dr. Supriya Bhalerao, Dr. Rajeshwari Kamat, Dr. Pradeep Shinde, Mr. Sudheer Kulkarni,
Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,**

Decision of the the Ethics Committee:

Recommended



Recommended with suggestions



Revision



Rejected



ATTESTED

Page 1 of 2


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

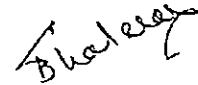
Suggestions/ Clarifications / Reasons/ Remarks:
Recommended for a period of : OneYear

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse



Dr. Basavaraj R Tubaki
(Member Secretary)



Dr. Supriya Bhalerao
(Chairperson)

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Kamataka

Page 2 of 2



Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/17/BSP/05

Protocol Title: "Evaluation Of Add On Efficacy & Safety Of An Ayurvedic Formulation In The Management Of Dengue Fever & Prevention Of Its Complications – A Double Blind Clinical Study"		
Principal Investigators/Co-investigators: Dr. B Sreenivasa Prasad, Dr. S. L. Hoti Dr. V A Kothiwale, Dr. Rekha Patil, Dr. Banappa S. Unger, Dr. Sukumar N Nandigoudar		
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya & KLE Ayurved Hospital, Shahapur, Belagavi		
<input checked="" type="checkbox"/> Review	<input type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review
Date of Review (DD/MM/YY): 25/03/2017		
Date of previous review, if revised application:		
Name of the Reviewers who attended the meeting: Dr. Supriya Bhalerao, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Mr. Sudheer Kulkarni, Mrs. Arati S. Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki, Dr. Giridhar Vedantam,		
Decision of the Ethics Committee:		
Recommended <input checked="" type="checkbox"/>	Recommended with suggestions <input type="checkbox"/>	
Revision <input type="checkbox"/>	Rejected <input type="checkbox"/>	

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Suggestions/ Clarifications / Reasons/ Remarks:


Following are the suggestions/clarifications of the EC

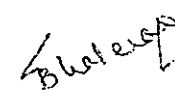
1. Title needs changes related to mentioning of complications. As prevention of complication is difficult to be assessed.

Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse


Dr. Basavaraj R Tubaki
(Member Secretary)


Dr. Supriya Bhalerao
(Chairperson)

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्
 आयुष तन्त्रालय, भारत सरकार
 जवाहर लाल नेहरू भारतीय चिकित्सा एवं परिसरार्थी अनुसंधान भवन
 01-65 सरकारी क्षेत्र, तन्त्रालय डी ब्लॉक, जनकपुरी नई दिल्ली- 110058

पत्र सं. 3-14/2017-सीसीआरएस/प्रशा./Dengue /1303
 आदेश

दिनांक : 28/07/2017

02 AUG 2017

केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्, नई दिल्ली के जन्त एवं रेगुलेशंस और काई-लॉज़, नियम - 50 के तहत संरणी-1 के आइटम न. 54 द्वारा पदान की हुई शक्तिओं का प्रयोग करते हुए मानविदेशक, केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्, नई दिल्ली, द्वारा अनुसंधान अधिकांसी प्रशरी, RARIMD, Bengaluru को Collaborative clinical research project "Evaluation of Ac on Efficacy & Safety of An Ayurvedic Formulation in the Management of Dengue Fever & Prevention of its complications - A Double Blind Clinical Study" का पूरा करने हेतु 03 participating institutes अर्थात् K.L.E. University's Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi - 590003 (Karnataka); ICMR - National Institute of Traditional Medicine, Nehru Nagar, Belagavi -590010 (Karnataka) एवं K.L.E. University's J.N. Medical College, Nehru Nagar, Belagavi -590010 (Karnataka) के लिए परिकोजना के बजट के तौर पर रुपये 98,23,307/- (रुपये अठानव लाख तैस हजार तीन सौ सात मात्र) की रकम प्रदान की जाती है। RARIMD, Bengaluru को उक्त 03 participating institutes के लिए परिकोजना के 1st Year के बजट रुपये 50,25,845/- (रुपये पचास लाख पच्चीस हजार आठ सौ पचास मात्र) की धरतरी को निम्न शर्तों, नियमों और शर्तों के अनुसार आनर्स्किम अग्रिम राशि के तौर पर निधि विमोचन करने की मंजूरी भी दी जाती है :-

बजट का अग्रवार विशाजन (वर्ष वार)

क्र. मांक	विवरण	प्रथम वर्ष (In Rs.)	द्वितीय वर्ष (In Rs.)	कुल (In Rs.)
A. K.L.E. University's Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi - 590003 (Karnataka)				
1.	जनशक्ति (वेतन)- एक एस.आर.एफ (Ayu.) @ Rs. 28,000 + 20% एच.आर.ए. = 33,600/- प्रति माह	4,03,200/-	4,03,200/-	8,06,400/-
2.	Recurring Expenditure	25,000/-	20,000/-	45,000/-
3.	Contingencies	15,000/-	10,000/-	25,000/-
4.	Travel	50,000/-	50,000/-	1,00,000/-
5.	Overhead Charges (5%)	25,820/-	23,000/-	48,820/-
	कुल	5,19,020/-	5,06,200/-	10,25,220/-
B. ICMR - National Institute of Traditional Medicine, Nagar, Belagavi -590010 (Karnataka)				
1.	जनशक्ति (वेतन) एक एस.आर.एफ (Ayu.) @ Rs. 28,000 + 20% एच.आर.ए. = 33,600/- प्रति माह	4,03,200/-	4,03,200/-	8,06,400/-
	Recurring Expenditure	8,00,500/-	8,00,000/-	16,00,500/-
	Contingencies Miscellaneous	14,000/-	10,000/-	24,000/-
	Travel	25,000/-	25,000/-	50,000/-
	Overhead Charges (5%)	64,055/-	60,000/-	1,24,055/-
	कुल	13,07,755/-	12,98,200/-	26,05,955/-

Dr. V.A.Kothiwale
 Registrar

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 Belagavi-590 010, Karnataka

क्र. सं.	विवरण	प्रथम वर्ष (In Rs.)	द्वितीय वर्ष (In Rs.)	कुल (In Rs.)
C. K.L.E. University's J.N. Medical College, Nehru Nagar, Belagavi -590010 (Karnataka)				
1	जनशक्ति (वेतन)			
	एक एच आर एफ (Ayu.) @ Rs. 28,000 + 20% एच.आर.ए. = 33,600/- प्रति माह	4,03,200/-	4,03,200/-	8,06,400/-
2	Recurring Expenditure	25,45,830/-	23,50,000/-	48,95,830/-
3	Contingencies Miscellaneous	15,000/-	10,000/-	25,000/-
4	Travel	85,000/-	85,000/-	1,70,000/-
5	Overhead Charges (5%)	1,50,000/-	1,44,862/-	2,94,862/-
	कुल	31,99,030/-	29,93,062/-	61,92,092/-
	Grand Total	50,25,845/-	47,97,462/-	98,23,307/-

नियम एवं शर्तें:-

- परियोजना CCRAS Research Policy को अनुसरण करते हुए पूर्ण की जाएगी।
- अनुसंधान अधिकारी प्रभारी, RARIMD, Bengaluru द्वारा, after fulfilling the requisite formalities of MoU and IEC approval as per CCRAS Research Policy, तीन participating institutes अर्थात् K.L.E. University's Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi - 590003 (Karnataka); ICMR - National Institute of Traditional Medicine, Nehru Nagar, Belagavi -590010 (Karnataka) एवं K.L.E. University's J.N. Medical College, Nehru Nagar, Belagavi -590010 (Karnataka) के प्रथम वर्ष के व्यय हेतु ICMR-NITM, Belagavi को स्वीकृति आदेश CCRAS Research Policy के अनुसार जारी किया जाएगा एवं बजट विवरण के अनुसार आकस्मिक अंशों में हस्तांतरण किया जाएगा।
- The progress of the project in accordance with approved timeline and deliverable should be submitted to the Council Hqrs. on monthly basis in the prescribed format (Annexure-6 to CCRAS Research Policy). The final report should be sent in the prescribed format (Annexure-7 to CCRAS Research Policy) within two months from the date of completion of the project. एक तीन participating institutes अध्ययन प्रारंभ करने के बाद मासिक, तिमाही एवं वार्षिक प्रगति रिपोर्ट RARIMD, Bengaluru को प्रेषित करेंगे तथा RARIMD, Bengaluru एक प्रतिमाह संस्थानों की साप्ताहिक, तिमाही एवं वार्षिक प्रगति रिपोर्ट परिषद मुख्यालय को प्रेषित करेंगे।
- परियोजना के लिए किये जाने वाले खर्च को principles laid down in Chapter 6 of the General Financial Rules 2017 titled "Procurement of Goods and Services" को अनुसरण करते हुए किया जाएगा।
- Separate account will be maintained for the project by all the participating institutes and RARIMD Bangalore. Record of expenditure may be kept separately by respective PIs for audit purpose.
- यदि जरूरत हो तो परियोजना के बजट की शर्तोंनुसार अधिकतम सीमा में परिवर्तन करने के लिए प्रस्ताव RARIMD, Bengaluru द्वारा परिषद को भेजा जा सकता है।
- The funds released and spent will be subject to audit by sponsoring authority and Government audit system. On completion of the project, the Investigator from ICMR-NITM, Belagavi should submit the audited utilization certificate (UC) and audited statement of expenditure along with unspent balance (if any) through DD to the funding authority through RARIMD Bangalore.
- परिषद परियोजना के दौरान दिशा-निर्देश जारी करने का अधिकार सुरक्षित रखती है।
- परियोजना के तहत अध्ययनों से निकाली गई रिपोर्टों को परिषद की अनुमति के बिना किसी अन्य पार्टी को नहीं भेजा जाएगा। इन अध्ययनों से निकाले गए किसी भी राश पत्र / किसी भी अन्य सचर को परिषद की पूर्व अनुमति के बिना प्रकाशित नहीं किया जाएगा। संबंधित राश पत्र / किसी भी अन्य सचर का मूल रूप से परिषद द्वारा प्रकाशित किया जाएगा।
- इस परियोजना के तहत सहायता के लिए मंजूरी की गई अनुशक्ति किसी भी तदर्थ से अन्य अवशेष के लिए परिषद की जिम्मेदारी नहीं होगी। अनुशक्ति की सेवा को परियोजना के पूरा होने के तुरंत बाद समाप्त किया जा सकता है।
- संबिधान्तक कार्यकारी को अनुशक्ति के आधार पर नियोजित किया जा सकता है। इससे से किसी भी कार्यकारी को किसी भी तरीके से सीसीआरएफएल का अंतर्गत नहीं माना जाएगा।
- परियोजना का कार्यक्रम दो वर्ष (2 वर्ष) के लिए है।

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Belagavi-590 010, Karnataka

13 चिकित्सीय परीक्षण को आरंभ करने से पूर्व इसका CIR के तहत पंजीकरण Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi द्वारा किया जाए।

परियोजना के लिए व्यय, परिचय मुख्यालय कार्यालय के Budget से अनुसंधान गतिविधियों के तहत वित्तीय वर्ष 2017-18 से भिन्न जाना है।

(के आर राजन)
प्रशासनिक अधिकारी (प्रशा.)
वृत्त महानिदेशक

सेवा में,

प्रशा.अधि.-सह- अनुसंधान नोट की प्रॉटो के साथ, अनुसंधान अधिकारी प्रभारी, RARIMD, Bengaluru को रुपये
लेखा अधिकारी - 50,25,845/- (रुपये पचास लाख पचास हजार आठ हज़ार 250 पैंतालीस मात्र) का आकस्मिक अग्रिम
सीसीआरएएस, विभाजन करने के लिए आगे की कार्यवाई हेतु प्रेषित है।
नई दिल्ली

प्रतिलिपि:-

1. अनुसंधान अधिकारी प्रभारी, RARIMD, Bengaluru - इस अनुरोध के साथ कि after fulfilling the requisite formalities of MoU and IEC approval as per CCRAS Research Policy, परियोजना संबंधी प्रथम वर्ष के व्यय हेतु ICMR - National Institute of Traditional Medicine, Nehru Nagar, Belagavi -590010 (Karnataka) को स्वीकृति आदेश जारी करने एवं प्रथम वर्ष के बजट विभाजन के अनुसार आकस्मिक अग्रिम राशि release करने की कृपा करें।
2. Dr. B.S Prasad, Principal, PI, K.L.E. University's Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi - 590003 (Karnataka).
3. महानिदेशक सीसीआरएएस, नई दिल्ली के वरिष्ठ निजी सचिव।
4. उप महानिदेशक, सीसीआरएएस, नई दिल्ली के निजी सचिव।
5. उप निदेशक (प्रशा.) सीसीआरएएस, नई दिल्ली के निजी सचिव।
6. डॉ. टी. महेशवर, अनुसंधान अधिकारी (आयु.), प्रोग्राम अधिकारी, सीसीआरएएस, नई दिल्ली।
7. डॉ. वी. एस. रागा, अनुसंधान अधिकारी (आयु.), नॉडल अधिकारी, सीसीआरएएस, नई दिल्ली।
8. डॉ. श्रुति खंडरी, अनुसंधान अधिकारी (आयु.), नॉडल अधिकारी, सीसीआरएएस, नई दिल्ली।
9. सौख्यकीय अधिकारी, सीसीआरएएस, नई दिल्ली।
10. डॉ. आदर्श कुमार, सहायक निदेशक (आयु.), परियोजना समन्वयक, सीसीआरएएस, नई दिल्ली।
11. Principal, PI, K.L.E. University's Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi- 590003 (Karnataka).
12. Head of the Institute, ICMR - National Institute of Traditional Medicine, Nehru Nagar, Belagavi - 590010 (Karnataka) - परियोजना के लिए स्विकृत बजट के अनुसार अन्य participating institutes अर्थात् K.L.E University's Shri B.M. Kankanwadi Ayurveda Mahavidyalaya, Shahapur, Belagavi एवं K.L.E. University's J.N. Medical College, Nehru Nagar, Belagavi का प्रथम वर्ष के बजट के अनुसार धनराशि आवंटित करने की कृपा करें।
13. Principal, K.L.E. University's J.N. Medical College, Nehru Nagar, Belagavi -590010 (Karnataka)
14. Dr. S.L Hoti, Investigator ICMR - National Institute of Traditional Medicine, Nehru Nagar, Belagavi - 590010 (Karnataka).

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Dr. V.A. Kothiwale
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INSTITUTIONAL ETHICS COMMITTEE

KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/14/BSP/02

Protocol Title: Evaluation of Anti-inflammatory and analgesic activities of Plumbago zeylanica L. root paste in osteoarthritis of Knee joints			
Principal Investigators/Co-investigators: Dr.B.S.Prasad, Dr Sukumar N Nandigoudar			
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &KLE Ayurved Hospital, Shahapur, Belgaum			
<input checked="" type="checkbox"/> New Review	<input type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review	
Date of Review (DD/MM/YY): 09.01.2015			
Date of previous review, if revised application:			
Name of the Reviewers who attended the meeting: Dr Subarna Roy, Dr.S.K.Patil, Dr. S. K. Hiremath, Dr.Sameer N Naik, Dr. Rajashree Kamat, Dr.B S Hebballi, Mrs Sarita Shirodkar, ShriNeminathKunne, Dr.Basavaraj R Tubaki			
Decision of the the Ethics Committee:			
Recommended	<input checked="" type="checkbox"/>	Recommended with suggestions	<input type="checkbox"/>
Revision	<input type="checkbox"/>	Rejected	<input type="checkbox"/>

ATTESTED

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Dr. V.A.Kothiwale
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Suggestions/ Clarifications / Reasons/ Remarks:

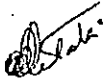
Following are the suggestions/clarifications of the EC-

1. Protocol was presented and was reviewed by the IE committee in which Dr Subarna Roy abstained from the review citing conflict of Interest.

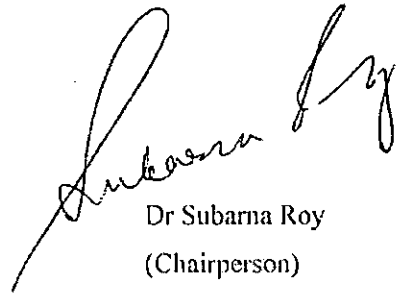
Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse



Dr. Basavaraj R Tubaki
(Member Secretary)



Dr Subarna Roy
(Chairperson)

ATTESTED

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Dr. V.A. Kothiwale
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KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka



Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/14/BSP/02

Protocol Title: Evaluation of analgesic and ant-inflammatory activities of Plumbago-zeylanica L. Root paste in osteoarthritis patients	
Principal Investigators/Co-investigators: Dr. B S Prasad, Dr. S L Hoti, Dr. Rajendra Bhandankar, Dr. Sudheer Yadawad, Dr. Harsha Hegde, Dr. Deepti Bagewadi, Dr. Sukumar N Nandigoudar	
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya & KLE Ayurved Hospital, Shahapur, Belagavi	
<input checked="" type="checkbox"/> Review	<input type="checkbox"/> Revised Review
<input type="checkbox"/> Expedited Review	
Date of Review (DD/MM/YY): 25/03/2017	
Date of previous review, if revised application:	
Name of the Reviewers who attended the meeting: Dr. Supriya Bhalerao, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Mr. Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki, Dr. Giridhar Vedantam,	
Decision of the the Ethics Committee:	
Recommended <input type="checkbox"/>	Recommended with suggestions <input checked="" type="checkbox"/>
Revision <input type="checkbox"/>	Rejected <input type="checkbox"/>

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Dr. V.A. Kothiwale
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Belagavi-590 010, Karnataka

Suggestions/ Clarifications / Reasons/ Remarks:

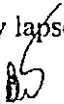
Following are the suggestions/clarifications of the EC

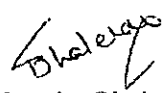
1. PIS : Need To include components elaborating possible manifestations related to local Toxicity/ Hypersensitivity to chitraka root bark paste. Rescue medication criteria etc
2. Local Toxicity/ Hypersensitivity to chitraka root bark paste can be evaluated before initiating the intervention in each patient.
3. Safety assessment could be evaluated through parameters like -CBC, LFT, RFT before & after intervention.
4. Mode of Intervention either Local Application/Oral Administration has to be clearly mentioned
5. Inclusion Criteria- Include cases belonging to Mild/Moderate categories only and exclude Pittaj shotha
6. Mention blood collecting volume.
7. Mention cytokines clearly

Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse


Dr. Basavaraj R Tubaki
(Member Secretary)


Dr. Supriya Bhalerao
(Chairperson)

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Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
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Belagavi-590 010, Kamataka

KLE / 14 / 14 / 02



INSTITUTIONAL ETHICS COMMITTEE
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belagavi

**COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS
COMMITTEE (IEC)**

Protocol No:BMK/14/BSP/02

Protocol Title: Evaluation of analgesic and anti-inflammatory activities of Plumbago zeylanica L. root paste in osteoarthritis patients			
Principal Investigators/Co-investigators: Dr.B S Prasad, Dr. S L Hoti, Dr.Rajendra Bhandankar, Dr.Sudheer Yadwad, Dr.Harsha Hegde, Dr. Deepti Bagewadi, Dr.Sukumar N Nandigoudar			
Name & Address of Institution: KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belagavi			
<input type="checkbox"/> New Review	<input checked="" type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review	
Date of Review (DD/MM/YY):20.03.2018			
Date of previous review, if revised application:09.01.2015			
Name of the Reviewers who attended the meeting: Dr. Supriya Bhalerao, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki, Dr.Aziz Dr.Giridhar V, Col.Ishwar Hurkadli			
Decision of the the Ethics Committee:			
Recommended	<input checked="" type="checkbox"/>	Recommended with suggestions	<input type="checkbox"/>
Revision	<input type="checkbox"/>	Rejected	<input type="checkbox"/>

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 1 of 2

Suggestions/ Clarifications / Reasons/ Remarks:

Recommended for a period of : One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Dr. Supriya Bhalerao
(Chairperson)

ATTESTED

Dr. V.A. Kolhiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 2 of 2

Tel: 265688960, 26588895

GRAM : SCIENTIFIC

FAX : 011-6868662

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, POST BOX NO. 4911
NEW DELHI - 110029

File No. 5/3/8/324/2016-ITR
Dated:13.01.2017

The Director
Regional Medical Research Center
Nehru Nagar,
Belgaum-590 010

Subject: Sanction of Budget allotment for the ICMR Ad-hoc Project entitled, " Evaluation of analgesic and anti-inflammatory activities of *Plumbago zeylanica* L. Rootpaste in osteoarthritis patients" under Dr. B.S. Prasad, Principal, BMK Ayurveda Mahavidyalaya.
Sir,

The Director General of the Council sanctions the above mentioned project with total budget allotment of Rs.51,06,076/- for the duration of 2 years w.e.f. ~~13.01.17~~ ^{16.1.2017} as per details provided in Annexure-1.

First Installment of grant-in-aid of Rs.13,49,973/- for the First Year will be released out of the first year budget of Rs.26,99,946/-. The payment of the grant will be made in two installment in the name of Head of the Institute through RTGS BANK ACCOUNT NUMBER: 0505201010915, MICR code of bank 590015002 (A copy of Mandate Form & cancelled cheque are enclosed).

The first installment of the grant will be paid generally as soon as report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent installment of the grant should be placed with the Council in advance.

1. The staff appointed on the project should be paid as indicated in the attached budget statement.
2. The approved duration of the research scheme is two years . The annual extension will be given after review of the work done on the research scheme during the previous year.
3. Five copies of the annual progress report of work done be submitted to the Council every year after completion of ten months of the project. Failure to submit the report in time may lead to termination of the project

ATTESTED

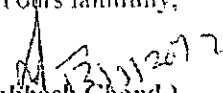
Contd.... 2/-

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

4. The Institute will maintain a separate account of the receipts and the expenditure incurred on the research scheme and will furnish an utilization certificate and an audited statement of the account pertaining to the grant.
5. The other terms and conditions are indicated in Annexure-1.
6. The receipt of this letter may please be acknowledged.

Yours faithfully,


(Subhash Chand)
Admin. Officer
for Director General

Copy together with a copy of the budget statement forwarded for info

rmation to:

1. Dr. ~~B.S.~~ Prasad, Principal, K.L.E. University's., Shri B.M.K. Ayurved Mahavidyalaya, Shahapur, Belgaum - 590 003, Karnataka
2. Copy together with two copies of the budget statement forwarded to Accounts Section-V, ICMR for information and necessary action. The expenditure on the account may be met from the provision made for **Division of ITR for Ad-hoc project** on grant-in-aid basis in the budget of the Council for the financial year 2016-17.
3. Copy together with two copies of the budget statement forwarded to budget section (Finance) ICMR for completion of the Council's budget.
4. IRIS cell, ICMR, ID.No. 2014-26060 dated 22.1.2015
RFC No. ITR/Ad-hoc/1/2016-17 dt.21.12.2016

for Director General

ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

5/3/8/324/2016-ITR

Date of start: 16.1.17

Duration: Two years

IRIS cell, ICMR, ID.No. 2014-26060 dated 22.1.2015

RFC No. RFC No. ITR/Ad-hoc/1/2016-17 dt.21.12.2016

Project entitled , " Evaluation of analgesic and anti-inflammatory activities of Plumbago zeylanica L.Rootpaste in osteoarthritis patients under Dr. B.S. Prasad, Principal, K.L.E. University's., Sri B.M.K. Ayurved Mahavidyalaya, Shahapur, Belgaum – 590 003, Karnataka

BUDGET ESTIMATE (Two years)
16.01.2017 to 15.01.2019

BMK Ayurveda Mahavidyalaya:

1.	Staff	1 st Year 16.01.2017 to 15.01.2018	2 nd Year
i)	Scientist B-Medical (2) (1-Orthopedician & 1-Ayurvedic physician) @ 55913/- + 5250/- (HRA)	14,67,912/-	14,67,912/-
ii)	Lab Technician (1) (Panchakarma Therapist) @ 18,000/- p.m	2,16,000/-	2,16,000/-
iii)	Multi Tasking Staff (1) @ 15,800/- p.m	1,89,600/-	1,89,600/-
2.	Contingencies		
	Recurring		
i)	Investigation Charges	3,64,800/-	2,22,600/-
ii)	Treatment Expenses (No. of patients (132) x Rs. 85)	6,970/-	4,250/-
iii)	Consumables	10,000/-	10,000/-
3.	Travel		
	Patients Travel (No of patients(132) x No of visits (9) x Rs 300)	2,21,400/-	1,35,000/-
	Field visits/ Recruitment camps/ Follow ups	1,00,000/-	50,000/-
4.	Miscellaneous (Stationeries/other charges)	10,000/-	5,000/-
5	Overhead charges (5%)	1,13,264/-	1,05,768/-
	Total Rs.	26,99,946/-	24,06,130/-
	Grand Total		Rs 51,06,076/-

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, POST BOX NO. 4911
NEW DELHI - 110029

File No. 5/3/8/324/2016-ITR

Dated: 13.01.2017

Subject: 1st Instt. of grant-in-aid for the First Year of ICMR Ad-hoc Project entitled, "Evaluation of analgesic and anti-inflammatory activities of Plumbago zeylanica L. Rootpaste in osteoarthritis patients" under Dr. B.S. Prasad, Principal, BMK Ayurveda Mahavidyalaya.

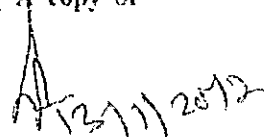
MEMORANDUM:

Reference this office letter of even number dated

The Director General, ICMR sanctions the payment of Rs. 13,49,973/- (Rupees thirteen lakh forty nine thousand nine hundred seventy three only) as the 1st Instt. of First year grant-in-aid for incurring expenditure in this connection with the above mentioned Research scheme. The amount of Rs. 13,49,973/- may be debited in the provision of Rs. 26,99,946/- made for the above mentioned research scheme for the 1st year i.e from 16.1.2017 to 15.1.2018

A formal bill for Rs. 13,49,973/- is sent herewith for payment to The Director, Regional Medical Research Centre (ICMR) Nehru Nagar Belgaum-590 010 Karnataka through RTGS: BANK ACCOUNT NUMBER: 0505201010915, MICR Code of Bank 590015002 (A copy of Mandate Form enclosed).

RFC No. ITR/Ad-hoc/1/2016-17 dt.21.12.2016


[Subhash Chand]
Admn. Officer

Accounts Section - V, ICMR

1. Dr. B.S. Prasad, Principal, K.L.E. University's., Shri B.M.K. Ayurved Mahavidyalaya, Shahapur, Belgaum - 590 003, Karnataka
2. The Director, Regional Medical Research Centre (ICMR), Nehru Nagar, Belgaum-590 010 Karnataka An amount of Rs. 13,49,973/- of 1st Instt. of 1st Year is being credited to your account as per detailed submitted by you. The grant has been sanctioned on the condition laid down in our letter referred to above.
3. IRIS cell, ICMR, ID.No. : 2014-26060 dated 22.1.2015

for Director-General

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

TERMS & CONDITIONS OF THE GRANT

- i) Approval of the research proposal and the grant being released in for the specific sanctioned and should be exclusively spent on this project within the stipulated time.
- ii) Expenditure should on no account exceed the budget sanctioned for the enquiry. Expenditure incurred over and above sanctioned amounts against one or more sub-heads of expenditure such as pay, allowances, contingencies etc. shall be met without reference to the ICMR by re-appropriation of savings under remaining sub-heads provided the total expenditure incurred during the financial year is within the overall sanctioned ceiling of the year.
- iii) No expenditure shall be incurred on items not sanctioned by the Council. Savings should also not be reappropriated for meeting or incurring expenditure on staff has not been sanctioned by the Council.
- iv) The grant paid by the Council shall be refunded in full be the Institution if and when the grantee concerned discontinues a scheme midway or does not follow the detailed technical programme laid down and approved.
- v) Receipts realized by the Project Officer and the sale proceeds if any, will be remitted to the Council as Miscellaneous receipts and should not be utilized for meeting expenditure on the scheme.
- vi) All facilities for the conduct of the research scheme, basic equipment and other ordinary laboratory chemicals, glassware furniture and other help as may be required for the smooth working of the scheme shall be provided by the institute.

STAFF

- vii) The staff employed on the research scheme will not be treated as employees of the Council and the deployment of such staff at the time of completion or termination of the project will not be the concern/responsibility of the Council. They will be subjected to administrative control of the Institution and will be appointed generally in accordance with the normal recruitment rules and procedure of the Institute.
- viii) The Council will not be liable to bear any expenditure on Pension/Provident Fund Contribution and/or leave salary contribution incurred or committed by the grantee Institution for persons appointed on deputation from other organization.

RELEASE OF FUNDS

- ix) The first installment of the grant will be paid as soon as a report regarding the commencement of the project and appointment of staff is received by the Council. The demand for payment of the subsequent installment of the grant be placed with the Council in the prescribed form.
- x) The Institute will maintain a separate audited account for this project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Council. The interest thus earned will be treated as a credit to be adjusted towards further installment of the grant.
- xi) The accounts will be subject to audit by the authorized auditors of the Institution. In case facilities are not available for such auditing, the account will be audited by the Council's own internal auditors. Latest be the end of December, following the financial year for which the grant is paid, and audit certificate, from the auditors to the effect the "the account have been audited and that the money was actually spent on the objects for which it was sanctioned" shall be submitted to the Council

ATTESTED


Dr. V.A. Kothiwate
Registrar

- xii) Further grants will be stopped unless audited statements of accounts utilization certificates are received within a period of one year after the end of the financial year for which grant.

STORES

- xiii) All expenditure and non-expendable articles required for work of the enquiry should be purchased in accordance with the procedure in vogue in the Institution. For permanent and semi-permanent assets acquired solely or mainly out of the grant a separate audited record in the form of register in the prescribed Performa enclosed shall be maintained the Institute. The term "assets" means (i) immovable property and (ii) movable property of capital nature where the value exceeds Rs 1000/-
- xiv) For other stores articles purchased from the Council's grant the Performa will be the same as is being used by the Institute. All the assets acquired from the grant will be property of the Council and should not, without the prior sanction of the council will be disposed of or encumbered or utilized for purposes other than those for which the grant has been sanctioned.

PUBLICATIONS

The financial assistance rendered by the Council should be acknowledged in the any published account of work of which the grant is give.

The Council published its own journal "Indian Journal of Medical Research" in Case it is proposed to publish the paper based on the work done under the auspices of the Council in Journals other than the IJMR, the name of the Journal in which it is proposed to published the paper may please be intimate. A reprint of the paper when published may please be sent to the Council for information and records.

Prior permission of the Council should be obtained before publication of any such papers in the foreign journal.

PAYMENTS

The Council shall have the right to take out patents in respect of invention/discoveries made under a scheme/project financed by the Council. The Officer-in-Charge or the staff employed on ICMR schemes shall not apply or obtained patents for any invention/discovery made by without prior approval of the Council.

All patents will be registered in the name of the Indian Council of Medical Research.

TERMINATION OF ENQUIRY

Prior permission of the Council shall be obtained if the investigator desired to discontinue the enquiry. The reasons for discontinuing the scheme should invariably be stated. The investigator should submit a complete and detailed report of work done by him on the project till the date of relief

Any unspent balance out of the funds given to the Institute shall be refunded to the ICMR on termination of the Scheme

A final report is required to be submitted within one month form the date of termination of the enquiry.

A list (in duplicate) of non expendable and expendable articles, together with property registers and suggestions for disposal of the articles should be sent to the Council within a month from the date of termination of the enquiry .

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



26588000, 26588707, 26589111, 26589414, 26589713, 26589912, 011 26589002, 011 26589201, 011 26589400, 011 26589600, 011 26589800, 011 26589900

Website: www.icmr.gov.in
E-mail: icmr@icmr.gov.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद्
INDIAN COUNCIL OF MEDICAL RESEARCH

श्री.रामलिंगस्वामी भवन, अन्नाजी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
SRIRAMALINGASWAMI BHAVAN, ANNARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

File No.5/3/8/324/2016-ITR

Dated 3.12.2018

To,

The Director
ICMR-National Institute of
Traditional Medicine
Nehru Nagar
Belagavi-590 010
Karnataka



Subject: Continuation of Ad-hoc Research Scheme entitled, "Evaluation of analgesic and anti-inflammatory activities of Plumbago zeylanica L. Rootpaste in osteoarthritis patients" under Dr. B. S. Prasad, BMK Ayurveda Mahavidyalaya

Sir,

The Director General of the Indian Council of Medical Research sanctions the continuation of above mentioned scheme with an allotment of Rs. 24,77,950/- (Rs. Twenty four lakhss seventy seven thousand nine hundred and fifty only) as detailed in the attached statement for the 2nd year from 16.01.2018 to 15.01.2019.

The grant will be released to the head of the institute in instalments during the financial year on receipt of the demand in the prescribed form (Appendix-1) as indicated below:

Total: Rs. 24,77,950/-

While asking for the release of the installment it may be ensured that the amount for the pay and allowances of the staff that are actually in position is included.

The other terms and conditions will remain same as mentioned in this office letter of even number dated 17.11.2016. This is issued with the concurrence of the Finance Div. RFC No. ITR/Ad-hoc/1/2016-17 dt. 21.12.2016

The Unspent balance of amount of Rs. 7,41,757/- is available with the PI as per the SOE & U:C as on dt: 2.11.2018.

The receipt of this letter may kindly be acknowledged.

Yours faithfully

A. Wason
4/12/18

(A. Wason)

Admn. Officer

For Director General

Copy to:

1. Dr. B.S.Prasad, Principal, K.L.E University, Shri B.M.K. Ayurved Mahavidyalaya, Shahpur, Belagavi - 590003 Karnataka.
2. Copy together with two copies of the budget statement forwarded to Accounts Section-V, ICMR for information and necessary action. The expenditure on the account may be met from the provision made for Division of ITR for Ad-hoc project on grant-in-aid basis in the budget of the Council for the financial year 2018-19.
3. Copy together with two copies of the budget statement forwarded to budget section (Finance) ICMR for completion of the Council's budget.
4. IRIS cell, ICMR, ID.No. 2014-26060 dated 22.1.2015
RFC No. ITR/Ad-hoc/1/2016-17 dt. 21.12.2016

ATTESTED

h
Dr. V.A.Kothiwate
Registrar

For Director General

Dr. B.S.P.
KLE Academy of Higher Education and Research,
(Deemed to be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

File No. 5/3/8/324/2016-ITR

Date of start: 1.12.2016

Duration: Two years

IRIS cell, ICMR, ID.No. 2014-26060 dated 22.1.2015

RFC No. ITR/Ad-hoc/1/2016-17 dt. 21.12.2016

Project entitled "Evaluation of analgesic and anti-inflammatory activities of Plumbago zeylanica L. Rootpaste in osteoarthritis patients" under Dr. B. S. Prasad, BMK Ayurveda Mahavidyalaya

BUDGET ESTIMATE (2nd year)**16.01.2018 to 15.01.2019**

Sl. No.	Staff	2 nd Year
1.	Scientist B-Medical (2) (1-Orthopedician & 1-Ayurvedic physician) @ 55913/- + 5250/- (HRA) + 2100 (10% increment) =Rs. 63,263/-p.m.	15,18,312/-
	Lab Technician (1) (Panchakarma Therapist) @ 18,000/- p.m + 800 (10% increment) = Rs. 18,800/-	2,25,600/-
	Multi Tasking Staff (1) @ 15,800/- p.m + 700 (10% increment) = Rs. 16,500/-	1,98,000/-
2.	Contingencies Recurring	
i	Investigation Charges	2,22,600/-
ii	Treatment Expenses (No. of patients (132) x Rs. 85)	4,250/-
iii	Consumables	10,000/-
3.	Miscellaneous (Stationeries/other charges)	5,000/-
	Total	21,83,762
	Overhead charges (5%)	1,09,188/-
4.	Travel Patients Travel (No. of patients(132) x No. of visits (9) x Rs. 300)	1,35,000/-
	Field visits/ Recruitment camps/ Follow ups	50,000/-
	Grand Total	24,77,950/-

(Rupees twenty four lakhss seventy seven thousand nine hundred and fifty only)

Awason
4/12/18
Admn. Officer

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

INDIAN COUNCIL OF MEDICAL RESEARCH
ANNAPURNA, POST BOX NO. 19
NEW DELHI - 110029

IS/21/2016-ITR
Dated: 26.05.2017

Subject: 2nd Instt. of first year grant-in-aid ICMR Ad-hoc Project entitled "Evaluation of analgesic and anti-inflammatory activities of Plumbago zeylanica L. Kooipate in osteoarthritis patients" under Dr. B.S. Prasad, Principal, B.M.K. Ayurveda Mahavidyalaya.

MEMORANDUM:

Reference this office letter of even number dated

The Director General, ICMR sanctioned the payment of Rs. 13,49,973/- (Rupees thirteen lakh forty nine thousand nine hundred seventy three only) as the 2nd Instt. of first year grant-in-aid for incurring expenditure in this connection with the above mentioned Research scheme. The amount of Rs. 13,49,973/- may be debited in the provision of Rs. 26,99,946/- made for the above mentioned research scheme for the 1st year i.e. from 16.1.2017 to 15.1.2018.

A formal bill for Rs. 13,49,973/- is sent herewith for payment to The Principal, K.L.E. University's., Shri B.M.K. Ayurved Mahavidyalaya, Shahapur, Belgaum - 590 003 through RTGS: BANK ACCOUNT NUMBER: 30563401262. MICR Code of Bank 590002009 (A copy of Mandate Form enclosed).

REC No. ITR/Ad-hoc/I/2016-17 dt.21.12.2016

[Subhash Chand]
Admn. Officer

Accounts Section - V, ICMR

1. Dr. B.S. Prasad, Principal, K.L.E. University's., Shri B.M.K. Ayurved Mahavidyalaya, Shahapur, Belgaum - 590 003, Karnataka
2. The Principal, K.L.E. University's., Shri B.M.K. Ayurved Mahavidyalaya, Shahapur, Belgaum - 590 003. An amount of Rs. 13,49,973/- of 2nd Instt. of first year is being credited to your account as per detailed submitted by you. The grant has been sanctioned on the condition laid down in our letter referred to above.
3. IRIS cell, ICMR, ID.No. : 2014-26060 dated 22.1.2015

for Director-General

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Ethics Committee for Research on Human Subjects
KAHER's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/17/BRT/01

Protocol Title: "A RANDOMIZED PLACEBO CONTROLLED PROSPECTIVE PHASE II CLINICAL STUDY OF AN AYURVEDIC CODED DRUG 'AYUSH D' ON GLYCEMIC CONTROL IN PREDIABETIC SUBJECTS". PROTOCOL VERSION-2019			
Principal Investigators/Co-investigators: Dr. B R Tubaki, Dr K V Mutnalli, Dr Amar Patil, Dr Rinky Thakur			
Name & Address of Institution: KAHER's University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &KLE Ayurved Hospital, Shahapur, Belgaum			
<input type="checkbox"/> New Review	<input checked="" type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review	
Date of Review (DD/MM/YY): 26/03/2019			
Date of previous review, if revised application: 21/07/2017, 9/10/2018			
Name of the Reviewers who attended the meeting: Dr. Supriya Bhalerao, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Dr Aziz Arbar, Mrs. Arati S. Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki			
Decision of the the Ethics Committee:			
Recommended	<input checked="" type="checkbox"/>	Recommended with suggestions	<input type="checkbox"/>
Revision	<input type="checkbox"/>	Rejected	<input type="checkbox"/>

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University w/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 1 of 2

Suggestions/ Clarifications / Reasons/ Remarks:

Following are the suggestions/clarifications of the EC-


Considering the IDRS (Indian Diabetes Risk Score), the age group can be modified as 30-70 years.

Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse


Dr. Basavaraj R. Tubaki
(Member Secretary)


Dr. Supriya Bhalerao
(Chairperson)

Page 2 of 2

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 2 of 2

320/MDC/10/18
22/10/18

केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद
राष्ट्रीय चिकित्सा एवं हार्मिडियल अनुसंधान शिवालय
एन.एस.एस. रोड, बेलगवी, कर्नाटक, जयपुरी-590010

क्र. 320/2017-वी.ए.आर.एस.वशा 45/4/17

दि. 21/06/2017

अदेश

10 JUL 2017

केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद, नई दिल्ली के स्लस एन रेगुलेशन और वाई-लॉज, नियम 50 के तहत माफ़ी 1 के आइटम नं. 54 द्वारा प्रदान की गई शोताओ का प्रयोग करते हुए एच SFC की 78th meeting के Agenda No 7C 3 द्वारा प्रदान की गई स्वीकृति के अनुसार सहभागी, केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद, नई दिल्ली, द्वारा सहयोग प्रदानकर्ता, RARIMD, Bengaluru को Collaborative clinical research project - "A Randomized Placebo Controlled Prospective Phase-II Clinical Study of an Ayurvedic Coded Drug 'AYUSH D' on Glycemic control in Pre diabetic Subjects" को पूरा करने हेतु 04 participating institutes अर्थात् RA Podar Ayurved Medical College, Mumbai, AIIMS, New Delhi, Shri B.M. Kankanwadi Ayurved Mahavidyalaya, Manipal, Belgaum एवं RARIMD, Bengaluru को परियोजना के 1st, 2nd एवं 3rd year के बजट विभाजन के अनुसार प्रति वर्ष के आधार पर आकस्मिक अग्रिम राशि release करने हेतु रुपये 1,55,95,200/- (रुपये एक करोड़ पचपन लाख पचास हजार दो सौ मात्र) एवं trial drugs at CCRAHQs के लिए रुपये 5,00,000/- (रुपये पाँच लाख मात्र) राशि योगदान रुपये 1,60,95,200/- (रुपये एक करोड़ पचपन लाख पचास हजार दो सौ मात्र) की धनराशि की स्वीकृति प्रदान की जाती है। RARIMD, Bengaluru को उक्त 04 participating institutes के लिए वित्तोजन के कुल बजट रुपये 1,55,95,200/- (रुपये एक करोड़ पचपन लाख पचास हजार दो सौ मात्र) की धनराशि की निम्न शीर्ष, नियम और शर्तों के अनुसार आकस्मिक अग्रिम राशि के तौर पर निधि विमोचन करने की सज़ूरी भी दी जाती है -

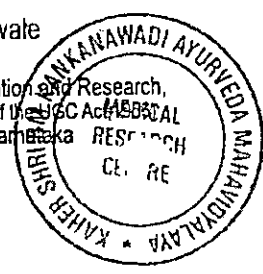
बजट का गहराज विभाजन (वर्ष वार)

क्र.	विवरण	वर्ष 1 (in Rs.)	द्वितीय वर्ष (in Rs.)	तृतीय वर्ष (in Rs.)	कुल (in Rs.)
A	RA Podar Ayurved Medical College, Dr Annie Besant Road, Worli, Mumbai - 400018				
1	जनशक्ति (वेतन)				
	एक एम.आर.एफ (Ayu//Medicine/Life Sciences @ Rs 28,000 + 30% एच आर ए = 36,400/- प्रति माह	4,36,800/-	4,36,800/-	2,18,400/-	10,92,000/-
2	Equipment Expenditure Laboratory investigations (creeping & etc., printing of CRFs etc)	5,00,000/-	5,00,000/-	2,00,000/-	12,00,000/-
3	Incidental support (@ Rs. 100/- per patient per visit)	25,000/-	25,000/-	2,800/-	52,800/-
4	Travel expenses (TA/DA)	1,50,000/-	1,50,000/-	50,000/-	3,50,000/-
5	Contingencies	1,00,000/-	1,00,000/-	50,000/-	2,50,000/-
6	All other expenses	1,00,000/-	1,00,000/-	50,000/-	2,50,000/-

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



क्र. सं.	विवरण	ए.ए.ए. (In Rs.)	द्वि-मास्य कार्य (In Rs.)	वृत्तीय वर्ष (In Rs.)	कुल (In Rs.)
C. Shri B.M. Kankarwadi Ayurved Mahavidyalaya, Shahapur, Belgaon					
1.	जनशक्ति (वेतन)				
	एक एस.आर.एफ. (Ayu./Medicine/Life Sciences @ Rs. 20,000/- + 20% एच.आर.ए. = 23,000/- प्रति माह	4,03,700/-	4,03,700/-	2,01,800/-	10,08,000/-
2.	Recurring Expenditure (Laboratory investigations, screening camps, printing of CFPs etc).	5,00,000/-	5,00,000/-	2,00,000/-	12,00,000/-
3.	Incidental support (@ Rs. 100/- per patient per visit)	25,000/-	25,000/-	2,800/-	52,800/-
4.	Travel expenses (TA/DA)				
5.	Contingency	1,50,000/-	1,00,000/-	50,000/-	3,00,000/-
	कुल	5,00,000/-	3,00,000/-	3,00,000/-	9,00,000/-
D. RARJMD, Bangalore					
1.	जनशक्ति (वेतन)				
	एक एस.आर.एफ. (Ayu./Medicine/Life Sciences @ Rs. 28,000/- + 30% एच.आर.ए. = 36,400/- प्रति माह	4,36,800/-	4,36,800/-	2,18,400/-	10,92,000/-
2.	Recurring Expenditure (Laboratory investigations, screening camps, printing of CFPs etc).	5,00,000/-	5,00,000/-	2,00,000/-	12,00,000/-
3.	Incidental support (@ Rs. 100/- per patient per visit)	25,000/-	25,000/-	2,800/-	52,800/-
4.	Travel expenses (TA/DA)				
5.	Contingency	1,50,000/-	1,00,000/-	50,000/-	3,00,000/-
6.	Budget for the training of project personnel	5,00,000/-	5,00,000/-	1,00,000/-	9,00,000/-
7.	Group insurance approx. @ 3 lac per annum	5,00,000/-			5,00,000/-
	कुल	10,00,000/-			10,00,000/-
	Grand Total	31,11,800/-	13,61,800/-	5,71,200/-	50,44,800/-
(रुपये एक करोड़ पचपन लाख ररारर हजार दोसो मात्र)					
E. CCRAS Headquarters, New Delhi					
	Trial drugs at CCRAS Hqs., New Delhi	5,00,000/-			5,00,000/-
	कुल				5,00,000/-
(रुपये पांच लाख मात्र)					

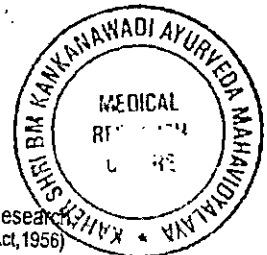
नियम एवं शर्तें:-

- परिचयना CCRAS Research Policy का अनुसरण करते हुए पूर्ण की जायेगी।
- सहायक निदेशना सार्व, RARJMD, Bangalore सार्व, after fulfilling the requisite formalities of MOU and IFC approval as per CCRAS Research Policy को अरर participating institutes अररर Poda Ayurved Medical College, Mumbai, AIIMS, New Delhi, Shri B.M. Kankarwadi Ayurved Mahavidyalaya, Shahapur, Belgaon को परिचयना की विर 2017-18 को CCRAS Research Policy के अनुसरण करी विर जायेगा एवं बरर विवरण के अनुसार अनुसरण करी विर जायेगा।
- The progress of the project shall be in accordance with approved timeline and deliverables. The report shall be submitted to the Council (Hqs.) in the prescribed format (Annexure 3 of CCRAS Policy). The final report shall be submitted to the Council (Hqs.) in the prescribed format (Annexure 3 of CCRAS Policy).

ATTESTED

Dr. V.A. Kothiwale
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5. Separately maintained for the project by all the participating institutes.
 6. expenditure incurred by respective PI for the purpose.
 7. यदि उपरोक्त बिन्दुओं के अन्तर्गत की शीर्षानुसार अधिसूचना के अन्तर्गत कार्य के लिए अग्रिम राशि का उपयोग किया जा सकता है।
 8. The funds released and spent will be subject to audit by sponsoring authority and Government audit system. On completion of the project, the Principal Investigator should submit the audited utilization certificate (UC) and audited statement of expenditure along with unspent balance (if any) through DD to the funding authority.
 9. परिषद परियोजना के दौरान निम्न निर्देश जारी करने का अधिकार सुरक्षित रखता है।
 10. परियोजना के तहत अध्ययनों से निकाली गई रिपोर्टों को परिषद की अनुमति के बिना किसी अन्य पार्टी को नहीं भेजा जाएगा। इन अध्ययनों से निकाले गए किसी भी शोध पत्र / किसी भी अन्य संचार को परिषद की पूर्व अनुमति के बिना प्रकाशित नहीं किया जाएगा। संशोधित शोध पत्र / किसी भी अन्य संचार को परिषद की पूर्व अनुमति के बिना प्रकाशित किया जाएगा।
 11. इस परियोजना के तहत सहायता के लिए मंजूर की गई जनशक्ति किसी भी तरह से आगे अवशोषण के लिए परिषद की जिम्मेदारी नहीं होगी। जनशक्ति की सेवा को परियोजना के पूरा होने के तुरंत बाद समाप्त किया जा सकता है।
 12. संबद्धतात्मक कर्मचारियों को अनुबंध के आधार पर नियोजित किया जा सकता है। इनमें से किसी भी कर्मचारी को किसी भी तरीके से सीसीआरएस का कर्मचारी नहीं माना जाएगा।
 13. परियोजना का कार्यकाल दो वर्ष एवं छह महीने (2½ वर्ष) के लिए है।
 14. चिकित्सीय परीक्षण को आरंभ करने से पूर्व इसका CTR के तहत पंजीकरण RARIMD, Bengaluru द्वारा किया जाए।
- परियोजना के लिए दृश्य, परिषद मुख्यालय कार्यालय के Budget से, अनुसंधान गतिविधियों के तहत वित्तीय वर्ष 2017-18 से किया जाना है।

(के आर राजन)
प्रशासनिक अधिकारी (प्रशा.)
कृते महानिदेशक


शेक नं.

- प्रश. अधि. संशु. लेखा अधिकारी, सीसीआरएस, नई दिल्ली
- अनुमोदित नोट की फॉटो कॉपी संलग्न है। आप से अनुरोध है कि -
- क) रुपये 1,55,95,200/- (रुपये एक करोड़ पचास हजार दो सौ मात्र) की धनराशि को अनुसंधान अधिकारी प्रभारी, RARIMD, Bengaluru को आकस्मिक अधिसूचना के तहत पर निधि विमोचन करने की कृपा करें।
- ख) रुपये 5,00,000/- (रुपये पांच लाख मात्र) की धनराशि को CCRRAS Hqs के लिए earmark करने की कृपा करें। The account may be kept separately. The funds will be released to the concerned firms/Agencies/Parties on recommendation of Program Officer of the project subject to approval of Director General, CCRRAS

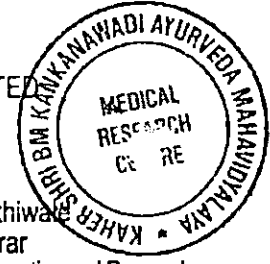
प्रतिलिपि:

1. अनुसंधान अधिकारी प्रभारी, RARIMD, Bengaluru - इस अनुरोध के साथ कि, after fulfilling the requisite formalities of Memo and CCRRAS Research Policy, तीन अन्य participating institutes अर्थात् Podar Ayurved Medical College, Mumbai, AIIMS, New Delhi, श्री B.M. Kankanwadi Ayurved Mahavidyalaya, Shahapur Belgaurn, को परियोजना के लिए समान राशि जारी करने के लिए संबंधित Institutes को परिषद के द्वारा अनुसंधान परिसर के तहत विमोचन करने की कृपा करें।
2. Dr. V.A. Kothiwale, H. R.O. (Secy.) Principal Investigator, RARIMD, Bengaluru
3. Dr. V.A. Kothiwale, H. R.O. (Secy.) Investigator RARIMD, Bengaluru
4. परिषद के अध्यक्ष को परिषद के अध्यक्ष के द्वारा
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ATTESTED



Dr. V.A. Kothiwale
Registrar



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Belagavi-590 010, Karnataka



अखिल भारतीय आयुर्वेद संस्थान
ALL INDIA INSTITUTE OF AYURVEDA (AIIA)
(आयुष्य मंत्रालय, भारत सरकार के अंतर्गत स्वयंचालित संस्थान)
(An Autonomous Organisation under the Ministry of AYUSH, Govt. of India)

स्वास्थ्य विभाग, नई दिल्ली

Date: 29 May, 2019

All Coordinators of IPVC's and PPVC's
Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha, Unani and
Homoeopathy Drugs.

Subject: Decisions taken in 4th PAC meeting - Regarding

With reference to the 4th PAC meeting held on 21st May 2019 at Ministry of AYUSH, it was decided that the program will be continued and following is communicated:

1. The Pharmacovigilance program for ASU & II Drugs will be continuing as before and extension shall be given to recruited manpower at IPVC's and PPVC's from April 2019 onwards.
2. The Unspent balance with each pharmacovigilance centre can be utilised for expenditure in the current financial year 2019-2020.
3. IPVC's shall meet the salary expenses of recruited manpower from the unspent balance available with them until they receive funds of further instalment.
4. If the funds for salary component at PPVC is exhausted, they shall meet the same expenditure from the head of 'Untied funds'.
5. The next instalment of funds for pharmacovigilance will be released as soon as the same is received from the Ministry of AYUSH, New Delhi.


This is for ensuring smooth functioning of the pharmacovigilance program at your centre. Further directions in this regard will be issued in due course of time.

Yours faithfully


29/5/19
(Prof. Tanuja Manoj Nesari)
Director

Copy to, Dr DC Katoch, Advisor, Ayurveda, Ministry of AYUSH.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University w/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

गौतमपुरी, सरिता विहार, मथुरा रोड, नई दिल्ली - 110076
Gautampuri, Sarita Vihar, Mathura road, New Delhi - 110076

Email: director.aia@gov.in Phone: 011-29948658 Fax: 011-299948660



अखिल भारतीय आयुर्वेद संस्थान
ALL INDIA INSTITUTE OF AYURVEDA (AIIA)
 (अयुर्वेद मंत्रालय, भारत सरकार के अधीन में स्थापित संस्थान)
 (An Autonomous Organization under the Ministry of AYUSH, Govt. of India)

F. No. B-11003/59/2017-AIIA/ 760

DE:08.06.2018

Sub: Release of funds under the Pherigacowigilance Program - Reg.

Dear Sir / Madam,

With reference to the subject cited above, it is to inform to you that approved financial assistance as approved by the Ministry of AYUSH, New Delhi is being credited into accounts of respective identified centres. From the sanctioned amount, a portion has been provided completely, however for other activities, 80% amount is being credited for all the identified intermediary centres. Details of the Intermediary and Peripheral centres with credited amount is enclosed herewith.

We request you to initiate appointing Program Associates / Assistants and Data Entry Operators as approved in the program by following the applicable guidelines and inform us.

Please acknowledge the credit of the amount in your account.

Thanking you.

[Signature]
 Prof. Tanuja Nesar
 Director

Enclosures:

1. As above

Dr. Ran Kothiwale
Ch
9/6/18

CRF
200 BC

संस्थान का पता: अयुर्वेद मंत्रालय, भारत सरकार - 110 075
 Connaught Place, Delhi Vidor, (Delhi) Road, New Delhi - 110 075
 E-mail: aiiainfo@aiia.org Email: aiiainfo@gmail.com Phone: 011-26104552 Fax: 011-26104550

OFFICE OF THE PRINCIPAL SHRI B. M. KARKAWADJI	
AYURVED MAHAVIDYALAYA A CONSTITUENT UNIT OF KANER	
SHARAPUR, BELGAUM-03	
DATE:	9/6/18
INWARD NO:	245

ATTESTED

[Signature]
 Dr. V.A. Kothiwale
 Registrar
 KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

INTERMEDIARY PHARMACOVIGILANCE CENTRES

	Name of the Centre	Credited Amount
1	National Institute of Homoeopathy, Salt Lake, Kolkata - 700 108.	₹ 16,76,000.00
2	Institute for Post Graduate Teaching and Research in Ayurveda, Jamnagar	₹ 16,76,000.00
3	National Institute of Ayurveda, Rajasthan 302004, India.	₹ 16,76,000.00
4	National Institute of Unani Medicine, Bangalore.	₹ 16,76,000.00
6	National Institute of Siddha, Tambaram Sanatorium, Chennai 47	₹ 16,76,000.00

PERIPHERAL PHARMACOVIGILANCE CENTRES

	Name of the Centre	Credited Amount
1	Regional Ayurveda Research Institute for Metabolic Disorders (CCRAS), GCP Ayurveda, Ashoka Pillar, Jayanagar, Bangalore - 560011	₹ 1,05,000.00
2	National Research Institute of Ayurvedic Drug Development, 4 CN Block, Sector-V, Bidhan Nagar, Kolkata - 700 061	₹ 1,05,000.00
3	Shri Sri Kankonewadi Ayurveda Maha Vidyalaya, Ghahapur, Belagavi	₹ 1,05,000.00
4	NEBAH, Shilong	₹ 1,05,000.00
5	VPSV Ayurveda College, Kottakkal, Malappuram, Kerala	₹ 1,05,000.00
6	SOM College of Ayurveda & Hospital, Hassan.	₹ 1,05,000.00
7	Regional Ayurveda Research Institute for Drug Development, Aamha, Gwalior.	₹ 1,05,000.00
8	Raja Ramdev Anandilal Podar Central Ayurveda Research Institute for Cancer, Podar Medical Campus, Worli, Mumbai - 400 018.	₹ 1,05,000.00
9	Central Ayurveda Research Institute for Cardiovascular Diseases, Punjabi bagh,	₹ 1,05,000.00
10	CSP Ayurveda Charek Samadhan, Khara Dabar, Delhi	₹ 1,05,000.00
11	University College of Ayurved, Dr SR Rajeshwari Ayurved University, Jodhpur	₹ 1,05,000.00
12	RG Post Graduate Ayurveda College, Paipra Himachal Pradesh	₹ 1,05,000.00
13	Govt. (Aho) Dhankantari Ayurved College Ujjain (MP)	₹ 1,05,000.00
14	Pt. Khushhal Ayurveda College, Bhopal, MP	₹ 1,05,000.00
15	Government Ayurved College, Raipur	₹ 1,05,000.00
16	Ayurved College, Bharati Vidyaapeeth, Pune	₹ 1,05,000.00
17	Institute of Medical Sciences, Banarasi Hindu University, Varanasi	₹ 1,05,000.00
18	Regional Research Institute of Homoeopathy, Dr. GGH Medical College Campus, Eluru Road, GUDIVADA - 521 301 Krishna Dist., AP	₹ 1,05,000.00
19	Dr. Anil Chatterjee Regional Research Institute for Homoeopathy, 50, Rajendra Chatterjee Road, Kolkata - 700035	₹ 1,05,000.00
20	National Homoeopathy Research Institute in Mental Health (NHRIMH) (Sachyechama puram P.O., Kottayam 686 582 Kerala)	₹ 1,05,000.00
21	Govt. Homoeopathic Medical College & Hospital, (PPVC), AYUSH Campus, beside Indrasol dam, M. A.C.T Hills, Bhopal, Pin - 462003, M.P.	₹ 1,05,000.00
22	Regional Research Institute for homoeopathy, Hall No - 04, Shopping centre, Sector-09, CBD, Belapur, New Mumbai - 400614	₹ 1,05,000.00
23	Central Research Institute for homoeopathy, Noida.	₹ 1,05,000.00
24	Regional Research Institute for Homoeopathy, Borsalal, PO Bellia, Guwahati	₹ 1,05,000.00


ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

25	Central Research Institute of Unani Medicine, Hyderabad	₹ 1,05,000.00
26	Central Research Institute of Unani Medicine, Lucknow	₹ 1,05,000.00
27	Regional Research Institute of Unani Medicine, Mumbai	₹ 1,05,000.00
28	Regional Research Institute of Unani Medicine, Chennai	₹ 1,05,000.00
29	Regional Research Institute of Unani Medicine, Coimbatore	₹ 1,05,000.00
30	Central Research Institute for Siddha, Chennai	₹ 1,05,000.00
31	Regional Research Institute for Siddha, Puducherry	₹ 1,05,000.00
32	Regional Research Institute for Siddha, Thiruvananthapuram	₹ 1,05,000.00
33	Govt. Siddha Medical College, Palayamkottai	₹ 1,05,000.00
34	AMO, Govt. Hospital Govt Hospital (Siddha Wing), Perundurai, Erode	₹ 1,05,000.00
35	Kulumbal, Govt District HQ Hospital (Siddha Wing), Tiruch	₹ 1,05,000.00
36	Govt. Siddha Medical College, Chennai	₹ 1,05,000.00
37	Govt District HQ Hospital (Siddha Wing), Dindigul	₹ 1,05,000.00
38	Govt District HQ Hospital (Siddha Wing), Gudalur	₹ 1,05,000.00
39	Govt. PHC, Valathi (Siddha Wing), Valapuran	₹ 1,05,000.00
40	MVAH Ayurveda College, Udaipur, Rajasthan	₹ 1,06,000.00
41	Uttarakhand Ayurved University, Haridwar	₹ 1,05,000.00

ATTESTED


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अखिल भारतीय आयुर्वेद संस्थान

ALL INDIA INSTITUTE OF AYURVEDA (AIIA)
(आयुष मंत्रालय, भारत सरकार के अंतर्गत स्वायत्त संस्थान)
(An Autonomous Organization under the Ministry of AYUSH, Govt. of India)

F. No. B-11003/5/9/2017-AIIA/4195

Dated 31 January, 2019

To,

Coordinators of IPvCC's and PPvC's
Central Sector Scheme of Pharmacovigilance for ASU & H Drugs.

Subject: Disbursement of Funds (2nd Instalment) - Reg

Respected Sir / Madam,

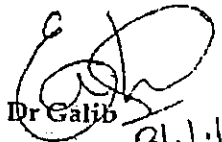
Good Morning

With reference to letter no. Z.25021/01/2017-DCC(AYUSH), dated 01/11/2018 having minutes of 2nd Project Sanctioning Committee meeting for the Central Sector Scheme of Pharmacovigilance for ASU & H Drugs; funds were sanctioned by the Ministry of AYUSH, New Delhi for the Salary component of Program Associates / Assistants for the identified IPvCC's and PPvC's for the next FOUR months. In addition to this, untied funds (@ Rs. 25,000 per each PPvC) were also sanctioned for all the identified PPvC's to meet the contingency expenses of their respective centres. The sanctioned funds have been disbursed to all the centres (Annexure-1) on 25.01.2019 from the account of Pharmacovigilance Program, All India Institute of Ayurveda, New Delhi to the respective centres.

In this regard; I am directed by the competent authority, AIIA to request all the Coordinators of the centres to kindly acknowledge the receipt of the distributed funds at the earliest on pharmacovigilance@ayush.gov.in after receiving the funds.

You are further requested to submit Utilization Certificate for the funds disbursed to you fulfilling the requirements sent through B-11002/5/9/2017-AIIA/4174 dated 28th January 2019.

Thanking you in anticipation.


Dr Galib
Coordinator 31.1.19

Enclosure:

1. Details of centres with funds disbursed into their accounts


Copy to:

Dr. DC Katoch, Advisor (Ayurveda), Ministry of AYUSH for information AT TESTED

Dr Pankaj
OS

Chr
2/2/19

OFFICE OF THE PERSONAL SECRETARY & IN-CHARGE
AYURVED ANNAHOTALAYA A CONSTITUENT UNIT OF KLE
SHAHAPUR, BELGAUM-03.
DATE 2/2/19
STAMP NO: 1194


Dr. V.A. Kothiwale
Registrar Page 1 of 3
KLE Academy of Higher Education and Research,
(Deemed to be University u/s 3 of the UGC Act, 1956)
Sri. Jagavi-590 010, Karnataka

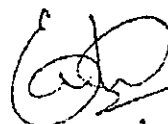
Details of Funds Disbursed to IPvCC's

S. No.	IPvCC	Amount disbursed	Remarks
1.	National Institute of Homoeopathy	₹ 1,60,000.00	Salary for Program Associate for 4 months @ 40000/- per month
2.	Director, National Institute of Ayurveda, Jaipur	₹ 1,60,000.00	
3.	National Institute of Unani Medicine, Bangalore	₹ 1,60,000.00	
4.	IPGT & RA, Jamnagar	₹ 1,60,000.00	
5.	National Institute of Siddha, Chennai	₹ 1,60,000.00	

Details of Funds Disbursed to PPvC's


S. No.	PPvC	Amount (Salary for Program Assistant for 4 months @ 25000/- per month)	Amount (Untied Funds)	Total Amount
1.	Regional Ayurveda Research Institute for Metabolic Disorders (CCRAS), GCP Annexe, Ashoka Pillar, Jayanagar, Bengaluru - 560011	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
2.	National Research Institute of Ayurvedic Drug Development, 4 CN Block, Sector-V, Bidhan Nagar, Kolkata- 700 091	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
3.	Shri BM Kanakanawadi Ayurveda Mahavidyalaya, Shahapur, Belagavi	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
4.	NEIAH, Shillong	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
5.	VPSV Ayurveda College, Kottakkal, Malappuram, Kerala	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
6.	SDM College of Ayurveda & Hospital, Hassan	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
7.	Regional Ayurveda Research Institute for Drug Development, Aamkho, Gwalior - 474009	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
8.	Raja Ramdev Anandilal Podar Central Ayurveda Research Institute for Cancer, Dr. Annie Besant Road, Worli, Mumbai - 400 018.	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
9.	Central Ayurveda Research Institute for Cardiovascular Diseases, Punjabibagh.	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
10.	University College of Ayurved, Dr SR Rajasthan Ayurved University, Jodhpur	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
11.	RG Post Graduate Ayurveda College, Paprola Himachal Pradesh	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
12.	Ayurved College, Bharati Vidyapeeth, Pune	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
13.	Uttarakhand Ayurved University Main Campus, Harrawala, Dehradun, Ultrakhand	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
14.	Regional Research Institute of Homoeopathy, Dr. GGH Medical College Campus, Eluru Road, GUDIVADA - 521 301 Krishna Dist., AP	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
15.	Dr. Anjali Chatterjee Regional Research Institute for Homoeopathy, 50, Rajendra Chatterjee Road, Kolkata - 700035	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
16.	National Homoeopathy Research Institute in Mental Health (NHRIMH) (Sachivothama puram P.O., Kottayam- 686 532 (Kerala)	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
17.	Govt Homoeopathic Medical College & Hospital, (PPvC), AYUSH Campus, beside kaliast dam, M, A.C.T Hills, Bhopal, MP	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
18.	Regional Research Institute for homoeopathy, Hall No - 04, Shopping centre, Sector - 09, CBD, Belapur, Navi Mumbai - 400614	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00

ATTESTED Page 2 of 3


31.1.19
Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

19.	Central Research Institute for homeopathy, Noida	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
20.	Regional Research Institute for Homoeopathy, Borsajai, PO Beltola, Guwahati - 781028	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
21.	Central Research Institute of Unani Medicine, Lucknow	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
22.	Central Research Institute for Siddha, Chennai	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
23.	Regional Research Institute for Siddha, Puducherry	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
24.	Regional Research Institute for Siddha, Thiruvananthapuram	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
25.	Govt. Siddha Medical College, Palayamkottai	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
26.	AMO, Govt. Hospital Govt Hospital (Siddha Wing), Perundurai, Erode.	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
27.	Govt. Siddha Medical College, Chennai	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
28.	Govt District HQ Hospital (Siddha Wing), Dindigul	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
29.	Govt District HQ Hospital (Siddha Wing), Cuddalore	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
30.	Govt. PHC, Valathi (Siddha Wing), Villupuram	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
31.	RRIUM, New Delhi	₹ 1,00,000.00	₹ 25,000.00	₹ 1,25,000.00
32.	CBP Ayurveda Charak Samsthan, Khara Dabar, Delhi	-	₹ 25,000.00	₹ 25,000.00
33.	Govt. (Auto) Dhanwantari Ayurved College Ujjain, MP	-	₹ 25,000.00	₹ 25,000.00
34.	Pt. Khushilal Ayurveda College, Bhopal, MP	-	₹ 25,000.00	₹ 25,000.00
35.	Government Ayurved College, Raipur	-	₹ 25,000.00	₹ 25,000.00
36.	Institute of Medical Sciences, BHU, Varanasi	-	₹ 25,000.00	₹ 25,000.00
37.	Central Research Institute of Unani Medicine, Hyderabad	-	₹ 25,000.00	₹ 25,000.00
38.	Regional Research Institute of Unani Medicine, Mumbai	-	₹ 25,000.00	₹ 25,000.00
39.	Regional Research Institute of Unani Medicine, Chennai	-	₹ 25,000.00	₹ 25,000.00
40.	Regional Research Institute of Unani Medicine, Srinagar	-	₹ 25,000.00	₹ 25,000.00
41.	Kulumani, Govt District HQ Hospital (Siddha Wing), Trichy	-	₹ 25,000.00	₹ 25,000.00
42.	MMM Ayurveda College, Udaipur, Rajasthan.	-	₹ 25,000.00	₹ 25,000.00


31.1.19

ATTESTED

Page 3 of 3


Dr. V.A.Kothiwate
Registrar

KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka



अखिल भारतीय आयुर्वेद संस्थान

ALL INDIA INSTITUTE OF AYURVEDA (AIIA)
(आयुष मंत्रालय, भारत सरकार के अंतर्गत स्वायत्त संस्थान)
(An Autonomous Organization under the Ministry of AYUSH Govt. of India)

F. No. B/11003/5/9/2017-AIIA/Fin./527

Dated: 28 May, 2019

Office Order No. 97/2019-20

Sanction of the Director, All India Institute of Ayurveda, New Delhi is hereby accorded for payment of Rs.17,00,000/- (Rupees Seventeen Lakhs only) to 17 Peripheral Centre for 3rd Instalment under "Pharmacovigilance Program" as per list enclosed. Amount Payable to each centre with bank details is mentioned in the list.

The expenditure will be met out of the budget of Project "Pharmacovigilance Program Initiative for ASU&H Drugs" for the financial year 2019-20.

(Prof. Dr. Tanuja Manoj Nesari)
Director

Copy to: -

1. Guard file
2. Office file
3. Accts. file

गौतमपुरी, सरिता विहार, मथुरा रोड, नई दिल्ली - 110076

Gautampuri, Sarita Vihar, Mathura road, NEW DELHI-110076

E-mail: accounts-section@aiia.gov.in

Phone: 011-29948658 ATTESTED Fax: 011-29848660

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

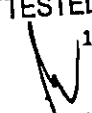
3RD INSTALLMENT FOR 17 PERIPHERAL PHAMACOVIGILANCE CENTRES (MAY-2019)

Sl No	Name of the Coordinator	Communicating Details		Name of the Centre	Account Details	Amount
		(E-mail)	Contact No.			
PPvCC- Centre						
Ayurveda						
1	Dr. Pradeep Soni, Lecturer, Dravyaguna	drpradeepsoni@gmail.com ppvcudaipur@gmail.com	7976260695 9414758052	MMM Ayurveda College, Udaipur, Rajasthan.	Principal, MMM Govt. Ayurved College, Udaipur	100,000.00
2	Prof. Manasi Deshpande	manasi08@gmail.com	9822493019	Ayurved College, Bharati Vidyapeeth, Pune	Name : Bank of India Account Number: 32979385081 IFSC Code: SBIN0008752	100000.00
3	Dr. Deepa Makhija, R.O. (Ay.)	drdeepamakhija@yahoo.co.in acr.delhi@gmail.com	Mob No. 9911331074	Central Ayurveda Research Institute for Cardiovascular Diseases, Punjabibagh, New Delhi	Indian Overseas Bank A/c No. 068701 000012994 IFSC Code : IOBA0000687	100000.00
4	Dr. Laxman PI at RRAP-CARIC Mumbai	acr-mumbai@gov.in dewa2007@rediffmail.com	Phone- 9086087677	Raja Ramdev Anandilal Podar Central Ayurveda Research Institute for Cancer, Podar Medical Campus, Dr. Annie Besant Road, Worli, Mumbai - 400 018.	State Bank of India (00290), Worli (North), Account No.- 10865762686 IFSC Code- SBIN0000290	100000.00
5	Dr Achintya Mitra Research Officer (Ayurveda) / Scientist-2	achintyamitra1@gmail.com nriadd.kolkata@gmail.com	9836727927	National Research Institute of Ayurvedic Drug Development, 4 CN Block, Sector-V, Bidhan Nagar, Kolkata- 700 091	Bank Name : State Bank of India Account Name : NRIADD, Kolkata (IMRP) Account No. : 34504103728 IFSC Code : SBIN0007816	100000.00

Dr. V.A. Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act 1956),
Belagavi-590 010, Karnataka

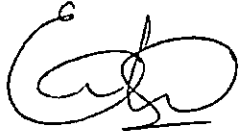
6	Dr Pankaja Savanur Reader, (Dept. of Kaumarabhritya)	drpysavanur@rediffmail.com mknovigilance.kaher@kleavurw.ordl.edu.in	mobile # 9448025369; 8494904971	Shri BM Kankanawadi Ayurveda Mahavidyalaya, Shahapur, Belagavi	Name of the Beneficiary: Principal Shri BM Kakanawadi Ayurved Mahavidyalaya, Shahapur, Belagavi. Account Number : 30563401362 Type of Account : Savings Account Name of the Bank: State Bank of India Branch Address: Near Arun Theatre, Congress Road, Tilakwadi, Belagavi IFSC Code : SBIN0004160 MICR Code : 590002009 PAN No. of Institute : AABTK0881E	100000.00
7	Dr. Shubhashree MN, Research Officer (Ay. Scientist -2)	shubhathejas@gmail.com nadribengaluru1@gmail.com nadri-bengaluru@gov.in nadri.bengaluru1@gmail.com	M-9448016968, Telefax: 080-26562030, Ph. 26572207	Regional Ayurveda Research Institute for Metabolic Disorders (CCRAS), GCP Annexe, Ashoka Pillar, Jayanagar, Bengaluru - 560011	Name of the Institute: Regional Ayurveda Institute for Metabolic Disorder Name of the Bank: State Bank of India, Bangalore city Account Number : 10509595790 IFSC Code : SBIN0040653 Branch: Raghuvanahalli (Kanakapura main Road), Bangalore -560062	100000.00
	Dr. Raghavendra Naik, Research Officer (Ay)	ayuraghu@gmail.com nadri-bengaluru@gov.in nadri.bengaluru1@gmail.com	M-8105683022, Telefax: 080-26562030, Ph. 26572207			
Homoeopathy Centres						
1	Dr. Chinta Raveendar	rriigudivada@gmail.com	Mob: 098491 26380	Regional Research Institute of Homoeopathy, Dr. GGH Medical College Campus, Eluru Road, GUDIVADA - 521 301 Krishna Dist., Andhra Pradesh	Name : REGIONAL RESEARCH INSTITUTE (H) Account No : 10607772179 Name of the Bank : STATE BANK OF INDIA IFSC Code : SBIN0000841 Name of the Branch : MAIN BRANCH, GUDIVADA	100,000.00
2	Dr. Ranjit Sonny, Research Officer (Homoeopathy) / S-1	rriihgua@gmail.com dranjitsonnymd@gmail.com	Tel. 0361-2306202, Mobile No. 09883203656	Regional Research Institute for Homoeopathy, Borsajai, PO Beltola, Guwahati - 781028	Name of the Bank: SBI, Kahilipara, Jatia Branch, Guwahati-781006 Account holder: Research Officer, In charge, Regional Research Institut (H), Guwahati-28. IFC Code: SBIN0004420. Office Telephone No. 0361/2306202 A/C No. 10281999617	100,000.00 ATTESTED  Dr. V.A. Kothiwale Registrar

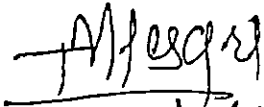
3	Dr. Pankaj Gupta	pankajgupta77@gmail.com	9999339018	Central Research Institute for homoeopathy, Noida (CRIH Noida gamil)	Office name and address: Dr. D.P. Rastogi Central Research Institute of Homoeopathy, A-1/1, Sector-24, Noida Bank name and address : State Bank of India, B-138, Sector-2, Behind Nirula, Noida-201301 (U.P.) A/c No: 30168382462 IFSC : SBIN0005936 MISC : 110002160 CIF No. 85090713795	100,000.00
4	Dr. DB Sarkar, Asst. Director, Incharge	drsarkardb@gmail.com ppverrikol.2018@gmail.com	Mob.9432086690 .8777046824	Dr. Anjali Chatterjee Regional Research Institute for Homoeopathy, 50, Rajendra Chatterjee Road, Kolkata - 700035	Dr. Anjali Chatterjee Regional Research Institute for Homoeopathy Account Number: 31567920705 State Bank of India - Alam Bazar, Kolkata - 700035 IFSC - SBIN0001356	100,000.00
5	Dr K C Muralidharan, Research Officer	dkcmurali@gmail.com	Mob: 8169959184	National Homoeopathy Research Institute in Mental Health (NHRIMH) (Sachivothama puram P.O., Kottayam-686 532(Kerala)	Name of Institute: NATIONAL HOMOEOPATHY RESEARCH INSTITUTE IN MENTAL HEALTH, KOTTAYAM Account No. : 30336005925 IFSC : SBIN0070128 Name of Bank : STATE BANK OF INDIA, CHINGAVANAM	100,000.00
6	Dr. Premnidhan Pal Chowdhury	dr.pcpal@rediffmail.com prashnrbho@mp.gov.in	Mob: 8889553676.	Govt. Homoeopathic Medical College & Hospital, (I'PvC), AYUSH Campus, beside kaliasot dam, M, A.C.T Hills, Bhopal, Pin - 462003, M.P.	Name of Bank account - PRINCIPAL AND SUPDT CUM CEO GOVT HOMOEOPATHIC COLLEGE Account Number - 30449943850 Name of the Bank - STATE BANK OF INDIA, NEHRU NAGAR BHOPAL IFSC Code - SBIN0010468	100,000.00
Unani- Centres						
1	Dr. Javed Inam Siddiqui	criumhyderabad@gmail.com	09849875295	Central Research Institute of Unani Medicine, Hyderabad	Director, CRIUM, Hyderabad 863720100001014 (Current Account) Bank of India, SR Nagar, Hyderabad IFSC Code :BKID0008637	100,000.00

ATTESTED


Dr. V.A. Kothiwale
RegistrarKLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi 590 010, Karnataka

2	Dr. Noman Anwar	nanomananwar@gmail.com	7358595174	Regional Research Institute of Unani Medicine, Chennai	Regional Research Institute of Unani Medicine, Chennai. Account Number: 800020100001905 Bank of India, Main Branch Chennai 600001 IFSC : BKID0008000	100,000.00
3	Dr. Mohd. Nafees Khan	mnkccrum@yahoo.com	09450390478 / 09140705710	Central Research Institute of Unani Medicine, Lucknow	Name: Central Research Institute of Unani Medicine, Kursi Road Lucknow Bank Account: 682120100000249 IFSC Code: BKID0006821 Name of the Bank: Bank of India, Terhi Pulia Branch, Lucknow	100,000.00
4	Dr. Shameem Ahmad Rather	shameem.rather_sr@gmail.com	9906957778 / 7889584083	Regional Research Institute of Unani Medicine, Srinagar	Name of the institute: Regional Research Institute of Unani Medicine Habbak Naseem Bagh, University Campus, Kashmir University, Srinagar. Account Number: 790010110001770 Name of the Bank: Bank of India IFSC CODE: BKID0007900 Branch : M.A.Road, Srinagar	100,000.00


28.5.19


28/5/19

ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Z.25021/01/2017- DCC (AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

AYUSH Bhawan
B-Block, GPO complex,
INA, New Delhi-110023
Dated: 14th March, 2018

Office Memorandum

Subject: Implementation of the Pharmacovigilance initiative for Ayurvedic, Siddha, Unani & Homoeopathic drugs-reg.

The undersigned is directed to refer to the subject mentioned above and to convey that consequent upon the approval of the Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha, Unani & Homoeopathic (ASU&H) Drugs, it is intended to develop a network of ASU&H Pharmacovigilance centres comprising of the All India Institute of Ayurveda (AIIA) as the National Pharmacovigilance Co-ordination Centre (NPvCC); 05 National Institutes (NIA, Jaipur; IPGT&RA, Jamnagar; NIS, Chennai; NIUM, Bengaluru; and NIH, Kolkata) as Intermediary Pharmacovigilance Centres (IPvCs); and 100 Peripheral Pharmacovigilance Centres (PPvCs).

2. To initiate the implementation of the Pharmacovigilance initiative, proposal of the AIIA dated 19th December, 2017 has been approved in the meeting of the Project Approval Committee held on 28th December, 2017 and the minutes thereto (Annexure-1), the list of 05 IPvCs and 43 PPvCs (Annexure-2) as well as the sanction order (Annexure-3) are enclosed herewith for information and for carrying out the intended activities. A copy of the Central Sector Scheme of Pharmacovigilance of Ayurveda, Siddha, Unani & Homoeopathic Drugs (Annexure-4) is forwarded herewith for the NPvCC to proceed for implementing the initiative in accordance with the provisions of the scheme and the financial estimates as per the sanction order involving the IPvCs and the PPvCs. Respective PPvCs may be informed accordingly to establish the system for ADR reporting and surveillance of misleading advertisements of ASU&H drugs.

Encl: as above


(Amit Ranjan)

Under Secretary to the Govt. of India

To

Prof. Tanuja Nesari,
Director,
All India Institute of Ayurveda (AIIA),
(National Pharmacovigilance Co-ordination Centre)
Sarita Vihar, New Delhi

Copy to:

1. Director, National Institute of Ayurveda-the designated IPvC, Jaipur, Rajasthan
2. Director, IPGT&RA-the designated IPvC, Jamnagar, Gujarat
3. Director, National Institute of Siddha-the designated IPvC, Chennai, Tamil Nadu
4. Director, National Institute of Unani Medicine-the designated IPvC, Bengaluru, Karnataka
5. Director, National Institute of Homoeopathy-the designated IPvCC, Kolkata, West Bengal.


(Amit Ranjan)

ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Amexule

Minutes of the Meeting of the Project Approval Committee (PAC) of the Central Sector Scheme of Pharmacovigilance of Ayurvedic, Siddha, Unani and Homoeopathic drugs

Project Approval Committee chaired by Secretary, Ministry of AYUSH met on 28th December, 2017 at 05.00 p.m. in the Ministry of AYUSH and considered the proposal of implementing pharmacovigilance program of AYUSH drugs during 2017-18 as received from the designated National Pharmacovigilance Coordination Centre (NPvCC) i.e. All India Institute of Ayurveda (AIIA), New Delhi. The following were present:

- i. Vaidya. Rajesh Kotecha, Secretary, Ministry of AYUSH-Chairman
- ii. Ms. Vijaya Srivastav, SS&FA, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.
- iii. Sh. Pramod Kumar Pathak, Joint Secretary, Ministry of AYUSH
- iv. Dr. D. C. Katoch, Advisor (Ayurveda), Ministry of AYUSH
- v. Dr. Satyapal Shani, Deputy Drugs Controller, CDSCO as DCG(I) representative
- vi. Dr. Ravindra Singh, Director (I/c), PCIM&H, Ghaziabad, U.P.
- vii. Dr. Dushyant Kumar, Research Officer (Ay.), Drug Control Cell, Ministry of AYUSH
- viii. Dr. Pradeep Dua, Research Officer (Ay.), Drug Control Cell, Ministry of AYUSH

The Project Approval Committee considered the recommendations of the Project Appraisal Committee regarding the proposal received from the National Pharmacovigilance Coordination Centre (NPvCC) and the request of Dean, Faculty of Ayurveda, BHU for Peripheral Pharmacovigilance Centre. The following decisions were taken:

1. The PAC approved the proposal of Rs. 1, 60, 60, 000/- (one crore sixty lakhs and sixty thousand rupees) for establishment of Pharmacovigilance matrix in the National Pharmacovigilance Coordination Centre (NPvCC); the five Intermediary Pharmacovigilance Centres (IPvCs); 43 Peripheral Pharmacovigilance Centres (PPvCs) including centre of Faculty of Ayurveda, Banaras Hindu University, Varanasi and 42 proposed by the NPvCC and recommended by the Project Appraisal Committee under the total budget of Rs. 1, 59, 60, 000/-.
2. Project manpower on contractual basis may be recruited by open mode following the codal formalities and the scheme guidelines.
3. Proposal for engagement of manpower for the Programme Management Unit in the Ministry of AYUSH and for organizing a National workshop in March, 2018 may be processed separately in file for approval of the IFD.
4. Awareness building initiatives may be taken up and in this regards initially, a press release may be given to the PIB for wider circulation in the media.
5. The NPvCC may send the composition of various committees as envisaged under the scheme for the approval of the Ministry.

The meeting ended with a vote of thanks to the Chair.

ATTESTED



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2

LIST OF APPROVED PHARMACOVIGILANCE CENTRES

INTERMEDIARY PHARMACOVIGILANCE CENTRES (IPvCs) - 05:

1. National Institute of Ayurveda, Jaipur, Rajasthan
2. IJGT&RA, Jamnagar, Gujarat
3. National Institute of Siddha, Chennai, Tamil Nadu
4. National Institute of Unani Medicine, Bengaluru, Karnataka
5. National Institute of Homeopathy, Kolkata, West Bengal.

PERIPHERAL PHARMACOVIGILANCE CENTRES (PFvCs) - 43:


AYURVEDA 19

1. Central Ayurveda Research Institute for Cardio Vascular Diseases, New Delhi (Jaipur)
2. Central Ayurveda Research Institute for Drug Development, Kolkata (Jamnagar)
3. Central Ayurveda Research Institute for Cancer, Mumbai (Jaipur)
4. Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore (Jamnagar)
5. Regional Ayurveda Research Institute for Drug Development, Gwalior (Jaipur)
6. RG Post Graduate Ayurveda College, Paprola, Himachal Pradesh (Jaipur)
7. Rishikul Govt. Ayurvedic PG College, Haridwar (Jaipur)
8. Government Ayurved College, Raipur (Jaipur)
9. North Eastern Institute of Ayurveda & Homeopathy (NEIAH), Shillong, Meghalaya (Jamnagar)
10. Ayurved College, Bharati Vidyapeeth, Pune (Jaipur)
11. VPSV Ayurved College, Kottakkal (Jamnagar)
12. KLE College of Ayurveda, Belgaum (Jamnagar)
13. SDM Ayurveda College, Hassan (Jamnagar)
14. Pt. Khushilal Ayurveda College, Bhopal (Jaipur)
15. Campus Ayurvedic College, Dr SR Rajasthan Ayurveda University, Jodhpur, Rajasthan (Jaipur)
16. MMM Ayurveda College, Udaipur, Rajasthan (Jaipur)
17. Ch. Brahma Prakash Gharak Ayurveda Samsthan, Delhi (Jaipur)
18. Govt. Dhanwantari Ayurvedic Medical College, Ujjain, Madhya Pradesh (Jaipur)
19. Faculty of Ayurveda, Banaras Hindu University, Varanasi, Uttar Pradesh (Jaipur)

SIDDHA 11

1. Siddha Central Research Institute, Chennai
2. Siddha Regional Research Institute, Puducherry

ATTESTED


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

3. Siddha Regional Research Institute, Thiruvananthapuram.
4. Govt Siddha Medical College, Palayamkottai
5. Govt Siddha Medical College, Chennai
6. ATSVS Govt Siddha Medical College, Munchirai, Kanyakumari
7. Govt District HQ Hospital (Siddha Wing), Erode
8. Govt District HQ Hospital (Siddha Wing), Dindigul
9. Govt District HQ Hospital (Siddha Wing), Trichy
10. Govt District HQ Hospital (Siddha Wing), Cuddalore
11. Govt District HQ Hospital (Siddha Wing), Villupuram

HOMOEOPATHY 07

1. Central Research Institute for Homoeopathy, Noida, UP
2. National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala
3. Regional Research Institute for Homoeopathy, Gudivada
4. Regional Research Institute for Homoeopathy, Guwahati
5. Regional Research Institute for Homoeopathy, Kolkata
6. Regional Research Institute for Homoeopathy, Mumbai
7. Government Homoeopathic Medical College and Hospital, Bhopal

UNANI 06

1. Central Research Institute of Unani Medicine, Hyderabad
2. Central Research Institute of Unani Medicine, Lucknow
3. Regional Research Institute of Unani Medicine, Mumbai
4. Regional Research Institute of Unani Medicine, Chennai
5. Regional Research Institute of Unani Medicine, Srinagar
6. Regional Research Institute of Unani Medicine, New Delhi

ATTESTED


Dr. V.A. Kothiwala
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Annexure 3

24021/01/2017-DCC (AYUSH)
Government of India
Ministry of AYUSH
DCC

AYUSH Bhawan, Block 'B'
GPO Complex, INA, New Delhi - 110023
Dated: 29th January, 2018

To,
The Pay & Accounts Officer (Sect.),
Ministry of Health & Family Welfare,
Nirman Bhavan, New Delhi - 110001

Subject: Release of 1st instalment of "Grant-in-aid-General" under PLAN 2017-18 to Director, All India Institute of Ayurveda, New Delhi an Autonomous Organization - the designated National Pharmacovigilance Co-ordination Centre (NPVCC) for the year 2017-18.

In exercise of the power delegated under DFPR - 1978, I am directed to convey the approval of the President to the sanction of Rs. 1,40,00,000/- (Rupees One crore forty lakhs only) 1st instalment of "Grant-in-aid-General" under PLAN 2017-18 to Director, All India Institute of Ayurveda, New Delhi an Autonomous Organization - the designated National Pharmacovigilance Co-ordination Centre (NPVCC) for the year 2017-18.

2. The sanction for Grant-in-aid is subject to the conditions and principles laid down in Rules 228 to 245 of General Financial Rule, 2017 as amended from time to time as well as other specific conditions that may be circulated from time to time.

3. The information with regard to availability of budget is as under:

(a)	Total Allocated Budget in BE 2017-18 (BE 2017-18)	Rs. 1,50,00,000/-
(b)	Expenditure prior to this sanctions	Nil
(c)	Amount of the current sanction	Rs. 1,40,00,000/-
(d)	Cumulative expenditure	Rs. 1,40,00,000/-
(e)	Balance Budget after the release	Rs. 10,00,000/-

The Grant-in-Aid is debitable to Demand No.05, Ministry of AYUSH under PLAN, 2017-18 under the following heads:

2210	Medical and Public Health (Major Head)
02001	Direction and Administration (Minor head),
16	Pharmacovigilance initiatives for ASU drugs
160031	Grant in aid General.

4. The sanction has been issued as per Rule 205 to 215 of General Finance Rules, 2005. The Grant-in-Aid will be subject to the conditions and principles enclosed in the letter.

5. It is further certified that the payee is not a defaulter in submission of UCs in past and has no UC as due for rendition under the rules under any scheme of the Department.

[Signature]

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ATTESTED


[Signature]
Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Kamataka

6. The accounts of the grantee institution/organization shall be open to inspection by the Sanctioning Authority and Audit, both by the Comptroller and Auditor General (CAG) of India under the provisions of CAG (DPC) Act, 1971 and Internal Audit Wing of the O/o CCA of the Ministry, whenever the institution or organization is called upon to do so.

7. This issues with the approval of IFD conveyed vide Ministry of AYUSH Concurrence Dy. No. C-2623/2017-18 dated 15.01.2018.

Yours faithfully,

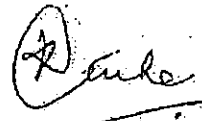


(K.B. Sinha)

Under Secretary to the Govt. of India

Copy forwarded to:-


1. Cash Section (AYUSH) with 2 spare copies. It is requested that a bill may be preferred through RTGS system for Rs. 1,40,00,000/- (Rupees One crore fortylaks only) in favour of Director, All India Institute of Ayurveda, New Delhi.
2. Director, All India Institute of Ayurveda, Sarita Vihar, New Delhi for information.
3. Internal Finance Division, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi.
4. AYUSH -E.III Section, Ministry of AYUSH.
5. Sanction Folder / Two copies for bills.



(K.B. Sinha)

Under Secretary to the Govt. of India

ATTESTED



Dr. V.A. Kothiwate

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KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Code of Peripheral Pharmacovigilance Centres for ADR Reporting

A / U / S / H	
Code	Ay-NIA/Code of Peripheral Centre/ADR Number/Year
	Ay-IPGT/Code of Peripheral Centre/ADR Number/Year
	Un-NIUM/Code of Peripheral Centre/ADR Number/Year
	Si-NIS/Code of Peripheral Centre/ADR Number/Year
	Ho-NIH/Code of Peripheral Centre/ADR Number/Year

Note:

1. ADR Number is to be generated by respective Peripheral Pharmacovigilance Centres (PPvC's) in a sequential manner. Code of Peripheral Pharmacovigilance centres is mentioned in the below tables.
2. For example: If Central Ayurveda Research Institute for Cancer, Mumbai, is reporting its first ADR, the code will be: Ay-NIA/002/1/2019.
3. Code for Intermediary Pharmacovigilance centres (IPvCC) will be: '000'.

AYURVEDA

➤ Under National Institute of Ayurveda, Jaipur, Rajasthan- IPvCC

S. No.	Peripheral Pharmacovigilance centres	Peripheral centre code
1.	Central Ayurveda Research Institute for Cardio Vascular Diseases, New Delhi	001
2.	Central Ayurveda Research Institute for Cancer, Mumbai	002
3.	Regional Ayurveda Research Institute for Drug Development, Gwalior	003
4.	RG Post Graduate Ayurveda College, Paprola, Himachal Pradesh	004
5.	Uttarakhand Ayurved University Dehradun, Uttarakhand	005
6.	Govt. Ayurved College, Raipur	006
7.	Ayurved College, Bhartiya Vidyapeth, Pune	007
8.	Pt. Kudhilal Ayurveda college, Bhopal	008
9.	Campus Ayurvedic College, Dr. SR Rajasthan Ayurveda University, Jodhpur, Rajasthan	009
10.	MMM Ayurveda College, Udaipur, Rajasthan	010
11.	Ch. Brahma Prakash Charak Ayurveda Samsthan, Delhi	011
12.	Govt. Dhanwantri Ayurvedic Medical College, Ujjain, Madhya Pradesh	012
13.	Faculty of Ayurveda, Banaras Hindu University, Varanasi, Uttar Pradesh	013

➤ Under IPGT & RA, Jamnagar, Gujarat- IPvCC

S. No.	Peripheral Pharmacovigilance centres	Peripheral centre code
1.	Central Ayurveda Research Institute for Drug Development, Kolkata	014
2.	Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore	015
3.	North Eastern Institute of Ayurveda & Homoeopathy (NEIAH),	016

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	Shillong, Meghalaya	
4.	VPSV Ayurved College, Kottakkal	017
5.	KLE, Belgaum College of Ayurveda	018
6.	SDM Ayurveda College, Hassan	019

SIDDHA

➤ Under National Institute of Siddha, Chennai, Tamil Nadu- IPvCC

S. No.	Peripheral Pharmacovigilance centres	Peripheral centre code
1.	Siddha Central Research Institute, Chennai	001
2.	Siddha Regional Research Institute, Puducherry	002
3.	Siddha Regional Research Institute, Thiruvananthapuram	003
4.	Govt. Siddha Medical College, Palayamkottai	004
5.	Govt. Siddha Medical College, Chennai	005
6.	Govt. District HQ Hospital (Siddha Wing), Erode	006
7.	Govt. District HQ Hospital (Siddha Wing), Dindigul	007
8.	Govt. District HQ Hospital (Siddha Wing), Trichy	008
9.	Govt. District HQ Hospital (Siddha Wing), Cuddalore	009
10.	Govt. District HQ Hospital (Siddha Wing), Villupuram	010

HOMOEOPATHY

➤ Under National Institute of Homoeopathy, Kolkata, West Bengal

S. No.	Peripheral Pharmacovigilance centre	Peripheral centre code
1.	Central Research Institute for Homoeopathy, Noida, UP	001
2.	National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala	002
3.	Regional Research Institute for Homoeopathy, Gudivada	003
4.	Regional Research Institute for Homoeopathy, Guwahati	004
5.	Regional Research Institute for Homoeopathy, Kolkata	005
6.	Regional Research Institute for Homoeopathy, Mumbai	006
7.	Govt. Homoeopathic Medical College and Hospital, Bhopal	007

UNANI

➤ Under National Institute of Unani Medicine, Bengaluru, Karnataka

S. No.	Peripheral Pharmacovigilance centre	Peripheral centre code
1.	Central Research Institute of Unani Medicine, Hyderabad	001
2.	Central Research Institute of Unani Medicine, Lucknow	002
3.	Regional Research Institute of Unani Medicine, Mumbai	003
4.	Regional Research Institute of Unani Medicine, Chennai	004
5.	Regional Research Institute of Unani Medicine, Srinagar	005
6.	Regional Research Institute of Unani Medicine, New Delhi	006


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka

ALI. INDIA COUNCIL FOR TECHNICAL EDUCATION
Nelson Mandela Marg, Vasant KUNDE New Delhi-110067

KLE UNIVERSITY COLLEGE OF
PHARMACY
J. N. M. C. Belagavi-10

Inward No. 1202 Date 16/10/17

Ref. No. 9-68/RIFD/MODROB/Policy-1/201-17

The Drawing and Disbursing Officer
Local

Sub: Release of Grant-in-Aid under Modernization and Removal of Obsolescence Scheme (MODROBS) for the year 2016-17 payable during the current financial year 2017-18.

Sir,

I am directed to convey the sanction of the Council for payment of Rs.1008000/- (Rupees Ten Lakh Eight Thousand Only) for the year 2016-17 under the Modernization and Removal of Obsolescence Scheme (MODROBS) to KLE College Of Pharmacy, Belgaum., J.N.Medical College Campus; Nehru Nagar-590010 Karnataka for meeting the expenditure for implementing the Scheme as per details given below:

1. Name of the Beneficiary Institution : KLE College Of Pharmacy, Belgaum., J.N.Medical College Campus, Nehru Nagar-590010 Karnataka
2. Chief Coordinator's Name & Deptt. : Dr. Anand Gadad, Deptt. Of Pharmacy
3. Title of the Project : Development, characterization and stability testing of Nanopharmaceuticals/ particulate drug delivery system for improved efficiency and quality
4. Grant-in-aid Sanctioned (80% in advance and 20% as reimbursement on submission of UC and other related documents) : Rs.1260000/- [Rs.1037647 /- for non-recurring and Rs.222353 /- for recurring expenditure]
5. Amount to be released : Rs. 1008000/-
6. Approved Duration (in years) : 2 Year

1. The sanctioned grant-in-aid is debit to the major Head 601.4.b MODROBS grant and is valid for payment during the financial year 2016-17.
2. The grant-in-aid of the grant shall be drawn by the Drawing and Disbursing Officer (DDO), All India Council for Technical Education, New Delhi on the Grants-in-aid bill and shall be disbursed to and credited to the account of The Principal / Director / Registrar KLE College Of Pharmacy, Belgaum., J.N.Medical College Campus, Nehru Nagar-590010 Karnataka.
3. The Institute is requested to verify the correctness of the under mention bank account/ RTGD submitted by them along with the proposals, in which the grant is being released. In case of any omission the same should be reported to AICTE immediately along with refund of entire grant.

Bank Name	Bank Branch and address	Account Holder's Name	Account Number	Type of Account	IFSC Code	Type of Institution	Institution's PAN No
Syndicate Bank	Nehru Nagar Branch, JNMC Campus, Nehru Nagar, Belagavi	Principal KLE College Of Pharmacy	5042010105461	Current Account	SYNB0000504	Private (Deemed University)	AABTK0881E

4. The date of release of the grant by AICTE shall be taken as the date of commencement of the project. The Principal / Director / Registrar shall intimate about the receipt of the grant to AICTE. Any Expenditure incurred prior to the issuance of the approval letter will not be allowed to be adjusted in the grant and if the Institution / University do not take the project work within one month of the receipt of the grant, the approval shall ipso facto lapse.
5. Each project sanctioned by AICTE is assigned a specific Ref. No. given on the pre-page. All correspondences related to the project must contain this number along with year of sanction of the project; failing which correspondence will not be entertained.
6. The accounts of the grantee which are liable to be audited by the Council or Comptroller and Audited General of India or by any Officer designated for the purpose.
7. The institute/University shall not charge any overheads on this project and will provide all the administrative support for completion of the project.



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Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University w/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Contd...2/-

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8. The grantee shall utilize grants on only approved items of expenditure (list enclosed). However in case the grantee wishes to recast the project, approval of the Council must be obtained for the revised item of expenditure and they will maintain proper accounts of the expenditure as per the norms/procedures of AICTE/Government of India.
9. The assets acquired wholly or substantially out of All India Council for Technical Education's grant shall not be disposed or encumbered or utilize for the purpose other than those for which the Grant was given without proper sanction of the All India Council for Technical Education and should at any time the institution cease to function, such assets shall revert to the All India Council for Technical Education.
10. The grantee shall maintain an audited record of assets acquired wholly or substantially out of the grant-in-aid and a register or assets shall be maintained by the Institute in the prescribed form i.e. GFR-19.
11. The amount of interest accrued on the grant should be treated as part of the grant to be utilized for that particular project. However, the interest amount accrued along with grant disbursed should not exceed the total grant sanctioned for the project. The Institute receiving the grant should reflect the same in the audited statement of accounts/ utilization certificate and may either refund the interest amount to AICTE or AICTE should adjust the same in the next installment of grant before releasing.
12. Since the duration of the project is for two years, the request for reimbursement of 20% of remaining amount shall be made with UC and other related documents in such a way that the entire project is completed in the prescribed period of two years.
13. The Annual Progress Report in the prescribed format along with Statement of Expenditure and Audited Utilization Certificate shall be submitted to AICTE not later than one month after completion.
14. Project Completion Report (PCR) in the prescribed format along with the Audited Statement of Expenditure indicating expenditure incurred in the total duration of the project in the prescribed format, utilization in the format and GFR-19 shall be submitted to the Council.
15. The Utilization Certificate (UC) supported by Audited Statement of Expenditure to the effect that the grant has been utilized for the purpose for which it has been sanctioned shall be furnished to the All India Council for Technical Education immediately after completion of the project. It should contain the head-wise break up of expenditure made from the grant-in-aid provided by the Council.
16. The grantee shall follow the terms and conditions of Modernization and Removal of Obsolescence (MODROBS) as laid down in the scheme details under AICTE AQIS 2016-17.
17. The Grantee shall fully implement the official language policy of Union Government and comply with the official language Act, 1963 and official language (use of official purposes of the Union Rules, 1976 etc.)
18. The University / Institute receiving grant under MODROB is expected to put up a plaque at the main entrance of the Lab/Department, which has been modernized using the grant. All the equipment procured through the project should be super scribed with AICTE project file number.
19. The funds to the extent are available under the scheme.
20. The sanction issues in exercise of the powers delegated to the Council. It is also certified that grant-in-aid is being released in conformity with the Rules and Regulation of the scheme.

Yours Sincerely,

(Dileep N. Malkhede)
Advisor (RIFD)

Copy forwarded for information and necessary action to:

08 SEP 2017

1. The Principal / Director / Registrar,
KLE College Of Pharmacy, Belgaum.,
J.N.Medical College Campus, Nehru Nagar-590010
Karnataka
2. Dr. Anand Gadad,
Deptt Of Pharmacy
J.N.Medical College Campus, Nehru Nagar-590010
Karnataka
3. Office of Director General of Audit,
General Revenues, AGCR Building, I.P. Estate,
New Delhi-110 002.

ATTESTED

Dr. V.A. Kothwale
Registrar

KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010, Karnataka



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ALL INDIA COUNCIL FOR TECHNICAL EDUCATION
Nelson Mandela Marg, Vasant Kunj, New Delhi - 110 067

Ref No.. 9-68/RIFD/MODROB/Policy-1/2016-17

Name of the Principal Investigator & Deptt Dr. Anand Gadad
Dept of PHARMACY.

Name of the Institution KLE College Of Pharmacy, Belgaum.,
J.N.Medical College Campus, Nehru
Nagar-590010, Karnataka

Title of the Project Development, characterization and
stability testing of
Nanopharmaceuticals/ particulate drug
delivery system for improved efficiency
and quality

Approved items for expenditure on purchase of machinery/equipments (Non-Recurring)

S.No.	Approved Items (As per proposal)
1	High Frequency Probe Ultrasonicators
2	Probes (Part of Above equipment)
3	Stability/Humidity Chambers

Total approved amount is Rs.1037647/-Non-recurring head and Rs.222353/- under Recurring head i.e. total approved amount is Rs.1260000/- (Rupees Twelve Lakh Sixty Thousand Only).


(Dileep N Malkhede)
Advisor (RIFD)

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka

