INSTITUTIONAL ETHICS COMMITTEE (IEC)

Ethics committee for biomedical and health research involving human participants

22.02.2024

STANDARD OPERATING PROCEDURE

Standard Operating Procedures for
Institutional Ethics Committee,
All India Institute of Ayurveda (AIIA), New Delhi

All India Institute of Ayurveda
Mathura Road, Gautampuri, Sarita Vihar, New Delhi – 110076

Standard Operating Procedures for
Institutional Ethics Committee,
All India Institute of Ayurveda) AIIA (, New Delhi

STANDARD OPERATING PROCEDURE

Particulars	Name and designation	Signature
Prepared by : **(Dated: 13.07.2017)**	**Prof (Dr) Tanuja Nesari**, MD, PhD *Director & Former Member Secretary,* *IEC* - All India Institute of Ayurveda, New Delhi – 110 076 **Late. Dr. Krishna Dalal,** *Former Research advisor & Member, IEC* - All India Institute of Ayurveda, New Delhi – 110 076	
Revised by : **(Dated: 02.062022)**	**Dr . V G Huddar**, MD, PhD *Member Secretary, IEC* Associate Professor Dept . of Kayachikitsa, All India Institute of Ayurveda, New Delhi – 110 076	
Reviewed by : **(Dated: 03.06.2022)**	**Dr . Galib R**, MD, PhD *Alternate Member Secretary, IEC* Associate Professor Dept . of RSBK, All India Institute of Ayurveda, New Delhi – 110 076	
Approve by: **(Dated: 06.06.2022)**	**Prof. (Dr). Tanuja Manoj Nesari** *Director,* All India Institute of Ayurveda New Delhi – 110 076	

PREFACE:

The Institutional Ethics Committee (IEC) established in 2017, is responsible for the scientific, ethical and regulatory oversight of researches conducted at All India Institute of Ayurveda, and serves to protect the rights and welfare of human subjects. Standard Operating Procedures (SOP) of IEC provide guidance to the members of IEC, Investigators, and other stakeholders involved in research. Adherence to these guidelines would help to promote and maintain the standards towards ethical conduct of research and protect the rights and well-being of research participants and communities. Various national and international bodies have developed and promulgated guidance documents for the ethical conduct of clinical research. The cornerstone of these ethical guidelines is that research should be subject to prior ethical review by a competent Institutional Ethics Committee. The present SOPs draw reference to these guidelines and documents and have been framed considering the variability in expertise, experience, training and capacity of IEC members at Tata Memorial Centre. A set of SOPs has been developed to maintain consistency in the process of review and continuous monitoring of research proposals by the IEC. The current set of revisions in the IEC SOPs has been made to update the existing SOPs, considering the changing laws, regulations, and guidelines for the conduct of medical research involving human participants as well as identifiable human material and data. All future revisions of the IEC SOPs will be made to reflect the changes in the national laws and guidelines and to keep pace with the international advances in the field of bioethics. The ultimate mandate of these SOPs will be to further the cause of conduct and adherence to the highest standards of human research.

I. Institutional Ethics Committee

Sl. No	Name and Designation	Signature
	Chairman	
1.	**Prof. S K Khandel** M.D, Ph.D. Former Professor, National Institute of Ayurveda, Jaipur, Rajasthan. Mob: 9414241707 E-mail: drkhandel@gmail.com	
	Member Secretary	
2.	**Dr. Vitthal Huddar**, M.D. Ph.D. Associate Professor, Dept. of Kayachikitsa, All India Institute of Ayurveda. New Delhi - 110 076 Mob: 9986697942 E-mail: dr.vghuddar@aiia.gov.in	
	Alternate Member Secretary	
3.	**Dr. Galib R**, M.D. Ph.D. Associate Professor, Dept. of RS & BK, All India Institute of Ayurveda. New Delhi - 110 076 Mob: 9428671275 Email: galib14@yahoo.co.in	
	Basic Medical Scientist	
4.	**Dr Ravishankar B,** MSc, PhD Former Head, Pharmacology lab, IPGT & RA, Jamnagar, Former Director, SDM centre for Research in Ayurveda and Allied Sciences, Udupi Mobile: +919483929319 E-mail: gravishankar2000@yahoo.com	
5.	**Prof. Subir Kumar Maulik**, MD, PhD Dept. of Pharmacology, AIIMS, New Delhi - 110 029 Mobile: 7065327696 E-mail: skmaulik@gmail.com	

Clinicians		
6.	**Prof Sujata Kadam**, MD, PhD Head, Dept of SRPT, AIIA, New Delhi. Mobile: 9818294577 E-mail: sujatadkadam@gmail.com	
7.	**Prof Manjusha R**, MD, PhD Head, Dept of Shalakya, AIIA, New Delhi Mobile: 7600901848 E-mail: bhatrajma2008@gmail.com	
8.	**Dr Rajagopala S**, MD, PhD Head, Dept of Kaumarabhritya, AIIA, New Delhi Mobile: 7600902564 E-mail: srajagopala@gmail.com	
Legal Expert		
9.	**Mrs Anita Pandey**, Legal advisor, F 98 Sector-41, Noida Mobile: 9811107701 Email: anitapandey3969@gmail.com	
Social Scientist		
10.	**Dr Vishwajanani Sattigeri** Head, CSIR-Traditional Knowledge Digital Library Unit 14, Satsang Vihar Marg, New Delhi - 110 067 Telephone: 91 11 47011291 / Mobile: 91 9818038495 Email: viswajanani.sattigeri@csir.res.in; headtkdl@csir.res.in	
Lay person		
11.	**Mrs Komal Tiwari** B-101, Pride Block, HRC Professional Hub, Vaibhav Khand, Indirapuram Ghaziabad (Up)Code- 201010 (Up) Mob: 8595111500, 9899546200 Email: tiwarikomal.11@gmail.com	
Special Member: (Basic scientist, Biostatistician)		
12.	**Prof. R M Pandey**, Head, Dept. of Biostatistics, AIIMS, New Delhi - 110 029 Mobile: 9868397940, 9811912117 Email: rmpandey@yahoo.com	

APPLICATION PROCEDURES:

a) OFFLINE MODE:

1. All proposals should be submitted (**after approval of IRB**) on any working day 6 weeks in advance of scheduled meeting in the prescribed application form, the details of which are included under "XII Documentation". The applicant may avail the SOP document from the Institutional Website http://www.aiia.gov.in
2. Three hard copies of proposal and one soft copy along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars/Chief Guide/Co-guide(s), forwarded through proper channel shall be submitted to member secretary IEC-AIIA. In his/her absence via any person nominated by Chairperson, receipt of the application will be acknowledged by the IEC office.
3. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting, to make a brief presentation (6-8 slides in IMRAD format) of the proposal, and to clarify the points raised by the members.
4. The decision of the committee on the proposal will be communicated in writing (IEC approval letter). If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
5. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. **will be charged an administrative fee/ processing fee of 5%**. The waive off of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like Ministry of AYUSH, ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non-Profitable Organizations etc.

Common Forms for Ethics Committee Review
can be downloaded from the below link

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b) ONLINE MODE:
Soft copy the final synopsis to be submitted online by clicking the link provided on the website of AIIA. www.aiia.gov.in. Just need to follow the steps to submit the synopsis through proper channel. Submitting online does not require offline submission.

FOLLOWING UP PROCEDURES FOR APPROVED PROPOSALS BY PI / SPONSOR:

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals based on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified in Annexure–4A, 4B 4C & 7 based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
4. Final report should be submitted at the end of study to IEC AIIA
5. Following instances and events will require the follow–up review/ Renewed Approval:
    a. Any protocol amendment likely to affect rights, safety or well–being of research subject of conduct of study.
    b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
    c. Any event or information that may affect the benefit/risk ratio of the study.
6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any new information related to the study should be communicated.
8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
9. Change of investigators/sites must be informed to the office of IEC.
10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB (Data Safety Management Board) may also be sought.
11. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

Initial Review Submission Form for Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Guide in case of thesis proposals.
6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants, precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, plan to withdraw or withhold standard therapies in the course of research, plan for statistical analysis of the study, ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any. Informed consent process, including patient information sheet and informed consent form in English and local language(s) (are mandatory. Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances should be attached. Source of funding and financial requirements for the project has to be detailed.
8. For any drug / device trial, relevant pre-clinical animal data and clinical trial data from other centers within the country/ other countries, if available.
9. Usefulness of the project / trial Expected 'benefits' to volunteers / community. 'Benefits' to other categories if any

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Annexure B

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF AIIA, NEW DELHI

OFFLINE:

Submit Three (3 (hard copies of the Research Proposal along with Covering letter and a 'soft copy' (word and PDF, to be mailed to iec-membersecretary@aiia.gov.in) along with the following information to the Member Secretary, IEC office, AIIA .
No research project shall be / can be started unless ethics clearance/approval is obtained .
Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee .
All submissions should be made in the prescribed Format of the IEC with signatures of all the investigators and forwarded by the competent authority . The submission must be accompanied with Participant Informed Consent Form) PICF (and Participant Information Sheet) PIS (, both in English and Hindi/Concerned local Language, in a simple layman's language, in a narrative form, directed to Participant/LAR, covering all the points given, before it can be considered for placing before the IEC . Also ensure that all the pages are numbered .

Project Submission Time : Submissions will be received on all working days . Proposals received till 15th of preceding month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting . All meetings of Institution Ethics Committee will be held as far as possible on every second Thursday of Jan, March, May, July, September, and November . The frequency will change depending upon the number of proposals and/or Gazette holidays which will be updated on the website : http://www.aiia.gov.in

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC Moreover if the approval is required in a particular format, the same may be sent to iec-membersecretary@aiia.gov.in. IEC reply to be submitted in tabular format addressing each comments of the IEC and changes made with page number where changes are made.

Amendment Submission : While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway

Annexure-C

PARTICIPANT INFORMATION SHEET) PIS (

To be modified as per the case

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent / guardian, in case of minor . While formulating the participant information sheet, the investigator must provide the subjects with the following information in English and Hindi, in a simple layman ' s language which can be understood by them, in a narrative form, directed to the participant / LAR, covering all the points :

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample) quantity in tea spoon full (to be taken
11. Costs and source of investigations, disposables, implants and drugs / contrast media
12. Telephone number / contact number of Principle investigator and Co–Investigator at the top of each page
13. In case of a drug trial :
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug / references should be provided
14. Self–certification should be given that the translation to vernacular language is correct

Annexure D

PARTICPANT INFORMED CONSENT FORM (PICF)

To be modified as per the case

Protocol Study number : _____

Patient identification number for this study : _____

Title of the project :

_____

_____

Name of Principal investigator : _____Tel . No) s (. _____

The contents of the information sheet dated _____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents . I confirm that I have had the opportunity to ask questions .

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail . I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal right being affected .

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIA . I give permission for these individuals to have access to my records .

I agree to take part in the above study .

_____ Date :

) Signatures / Left Thumb Impression (Place :

Name of Participant : _____Son / Daughter / spouse of : _____

Complete postal address : _____ This is to certify that the above consent has been obtained in my presence .

_____ Date :

Signatures of the Principal Investigator Place :

1) Witness – 1

_____

Signature

Address :

2) Witness – 2

_____

Signature

Address :

NB : Three copies should be made, one each for) 1 (Patient) 2 (Researcher) 3 (Institution) Investigators are advised to prepare the translation in simple understandable Hindi on their own (

Annexure E

सहभागी सुचित सहमति प्रपत्र

इस जाचं के लिए सहभागी पहचान नमबर_____

अनुसन्धान शीर्षक_____

मुख्य अन्वेषक का नाम _____ फोन नंबर: _____

मैंने दिनांक_____ के सूचना पत्र में दिये गए सभी तथ्यो को पड़ लिया हैं| मुझे समझ आने वालीं भाषा मैं विस्तारपूर्वक बत्ता दिया है और मैनें तथ्यो को भली भांति समझ लिया है| मैं पुष्टि करता हूँ कि मुझे प्रशन पुछने का अवसर दिया गया है|

मुझे अध्ययन की प्रकृति, उद्देश्य और इसके सम्भावित लाभ/जोखिमों और अध्ययन की सम्भावित अवधि अन्य प्रासंगिक जानकारी के बारे में विस्तार पुर्वक समझा दिया गया है | मैं समझाता हूँ कि इस अध्ययन में मेरी भागिधारी स्वेछिक है और इस अध्ययन से किसी भी समय बिना कोई कारण बताए, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हए अपना नाम वापिस ले सकता/सकती हैं |

मैं समझता हूँ कि इस अनुसन्धान में मेरी सहभागिता से मेरे बारे में एकत्र जानकारी और चिकित्सीय नोटों को एम्स अस्पताल के जिम्मेदार लोगो द्वारा देखा जायेगा| मैं इन व्यक्तियों को अपने रिकोर्ड देखने कि अनुमति प्रदान करता/करती हूँ |

मैं उपयुर्क्त अध्यन में भाग लेने के लिए अपनी सहमति प्रदान करता /करती हूँ |

सहभागी के हस्ताक्षर / बाएं अंगूठे का निशान दिनांक स्थान

सहभागी का नाम

पिता/पति का नाम

पूरा पता

यह प्रमाणित किया जाता हे कि उपयुर्क्त सहमति मेरी उपस्थति में ली गईं हैं |

मुख्य अन्वेषक के हस्ताक्षर दिनाक: स्थान:

१) गवाह के हस्ताक्षर

नाम

पता

२) गवाह के हस्ताक्षर

नाम

पता

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