Standard Operating Procedures
Institutional Ethics Committee (IEC-NIA)

Version 3; 1st August 2024

NATIONAL INSTITUTE OF AYURVEDA
(Deemed to be University) Jaipur- 302002

STANDARD OPERATING PROCEDURES FOR INSTITUTIONAL ETHICS COMMITTEE (IEC-NIA)

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

Abbreviations

ASU	Ayurveda Siddha Unani
CDSCO	Central Drugs Standard Control Organization
COI	Conflict of Interest
CTRI	Clinical Trial Registry of India
DCGI	Drugs Controller General of India
HMSC	Health Ministry's Screening Committee
ICD	Informed Consent Document
ICMR	Indian Council of Medical Research
IEC-NIA	Institutional Ethics Committee- National Institute of Ayurveda
LAR	Legally Approved Representative
MoU	Memorandum of Understanding
PI	Principal Investigator
PIS	Patient Information Sheet
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
ToR	Terms of Reference

INDEX

1. INTRODUCTION

National Institute of Ayurveda (NIA), Deemed to be University (De novo) is an apex autonomous Institute under the aegis of Ministry of Ayush, Government of India.

NIA was conferred the Deemed to be University status under De novo category on 9th November 2020. And is the first Central Government funded Institute to be declared as Deemed to be University in the field of Ayush.

This achievement came as a recognition of NIA having 175 years of legacy and for promoting the growth and development of Ayurveda as a model Institute with high standards of Teaching, Training, Research, and Patient Care with a scientific outlook to the knowledge of Ayurvedic System of Healthcare.

NIA currently offers Academic Programmes in 20 disciplines of Ayurveda in all levels – Undergraduate (BAMS), Post Graduate (MD/MS/MSc), Post Doctoral (PhD), Diploma (DAN&P).

NIA has a 260 bedded NABH accredited Hospital to offer best quality OPD and IPD services to the public. The hospital is equipped with state of art Panchakarma Centre, modern OTs, Ventilator supported Emergency Care Beds, GMP Certified Pharmacy and well equipped NABL accredited Pathology laboratory.

NIA conducts quality multi-disciplinary researches in the field of Ayurveda involving in-vitro, in-vivo, clinical, laboratory based, Analytical, literary and survey studies.

The Institute has quality infrastructure to support these researches like Animal house, Pharmacognosy Lab, Phytochemistry Lab, Drug Testing Laboratory, Advanced Simulation Lab, etc.

Biomedical research involves a number of ethical issues that need to be addressed.

The Institutional Ethics Committee (IEC) plays an important role in guiding researchers in the ethical aspects associated with the biomedical research.

Apart from ethical issues, IEC also reviews the research proposals for the scientific relevance and risk involved in research.

IEC of NIA functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017 (ICMR National Ethical Guidelines)

2. OBJECTIVES OF THE STANDARD OPERATING PROCEDURES (SOPs)

The objectives of these SOPs are to:

- Contribute to the effective functioning of the Institutional Ethics Committee of National Institute of Ayurveda for human research.
- Establish a quality and consistent ethical review mechanism for health and biomedical research proposals.
- Comply with National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR, 2017), Drugs and Cosmetics Act (1940), Drugs and Cosmetics Rules (1945), and New Drugs and Clinical Trials Act and Rules (2019) and Ayush GCP Guidelines.

TERMS OF REFERENCE
OF
IEC-NIA

DATE OF IMPLEMENTATION: 1st August 2024

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3. Terms of reference (ToR) of Institutional Ethics Committee of National Institute of Ayurveda (IEC-NIA)

3.1 Purpose

The purpose of the Institutional Ethics Committee of NIA is to ensure that all research involving humans, conducted at the institution is carried out with the highest ethical standards, integrity, and responsibility, with the following objectives:

- Protect the rights, safety, and wellbeing of research participants.
- Promote ethical conduct of research, including transparency, accountability, and fairness.
- Ensure compliance with national and international regulations, guidelines, and standards for ethical research.
- Provide ethical guidance and support to researchers, students, and staff

3.2 Scope

This SOP applies to the constitution of the IEC-NIA. The NIE-IEC-NIA will review all research

projects undertaken in and by NIE for compliance with National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017, Ethical guidelines provided by ICMR – 2006 and MoHFW (Department of Health Research) Notification 20th January 2005 (Requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials), 30th January 2013 (Compensation in case of injury or death due to clinical trial), 1st February 2013 (Permission to conduct clinical trials), 8th February 2013 (Registration of Ethics Committee), ICH guidelines and CDSCO GCP Guidelines. Re-Registration of ethics committees on 27th Dec

2016 as per the provisions of rule 122 DD of drugs and cosmetics rules. The projects will also be reviewed with reference to the guidelines/regulations of the country of origin of the sponsor for international studies.

3.3 Responsibility

The IEC-NIA has the responsibility, within the Institution, for the following objectives:

a. Ensuring the competent review and evaluation of all the scientific and ethical aspects of research projects received compliance with the appropriate laws, and welfare of participants.

b. Creation, development, revision and implementation of SOPs /guidelines for the IEC-NIA

c. Continuing education and training programs of IEC-NIA members to ensure that they are qualified to perform their specific duties and maintain the quality of review

d. These ToR will be maintained in the office of IEC-NIA.

3.4 Authority under which IEC-NIA is constituted

The Vice Chancellor, National Institute of Ayurveda, deemed to be university, Jaipur, constituted the IEC, on 5th January 2024 via office order number F.10(05)/IEC/ACA/19078-83 in accordance with the guidelines laid down in the New Drugs and Clinical Trials Rules, 2019; National Ethical Guidelines for Biomedical Research on Human Participants by ICMR, 2017 and GCP guidelines for clinical trials in Ayurveda siddha and Unani medicine , 2013. The term for IEC-NIA is for Three (3) years.

3.5 Appointment of members of the IEC-NIA

The appointment of members of the IEC-NIA is the prerogative of the Vice chancellor, NIA. The appointment of the IEC member is confirmed after receipt of their consent to abide by the Good Clinical Practice (GCP) guidelines and maintenance of confidentiality. The Vice chancellor, NIA appoints coordinating/supporting staff for IEC who is supervised by the Member Secretary.

3.6 Composition of IEC-NIA

The number of members in present IEC-NIA is twelve (12). The IEC is multidisciplinary in composition and independent. As per the National Ethical Guidelines for Biomedical Research on Human Participants by ICMR and GCP guidelines for clinical trials in Ayurveda siddha and Unani medicine 2017, IEC-NIA has following categories of members:

- Chairperson – Non-affiliated
- Member Secretary – Affiliated
- Basic medical scientists – Non-affiliated/affiliated (one preferably pharmacologist and one from Dravyaguna/Rasashastra)
- Clinicians – Non-affiliated/affiliated
- Legal expert (1)– Non-affiliated/affiliated
- Social Scientist / representative of NGO / Philosopher / ethicist / theologian – Non-affiliated/affiliated
- Layperson from the community – Non-affiliated/affiliated
- One or more-woman members

3.7 Quorum requirements

- A minimum of five members must be present in the meeting.

- The quorum should include both medical, non-medical or technical and non-technical members.
- Minimum one non-affiliated member should be part of the quorum.
- Preferably the layperson should be part of the quorum.
- The quorum for reviewing regulatory clinical trials should be in accordance with current New Drugs and Clinical Trials Rules 2019 requirements.
- No decision is valid without fulfilment of the quorum.

3.8 Membership requirements for IEC

Every member of the IEC must:

- Provide an updated CV with signature
- Provide Consent letter to be a part of IEC
- Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines
- If not trained, must undergo training and submit training certificates within 6 months of appointment.
- Be willing to undergo training or update their skills/knowledge during their tenure
- Declare Conflict of Interest (COI) in accordance with the policy of the IEC, if applicable, at the appropriate time
- Sign a confidentiality and conflict of interest agreement/s

3.9 Tenure of Membership

- The appointment of the members would be for a period of three (3) years, after which they may be either replaced or reappointed with a fresh appointment letter prior to the end of tenure of members.
- At the end of 3 years, the committee will be reconstituted, and one-third of the members will be replaced by a defined procedure (those who have had the longest standing in the IEC-NIA shall be phased out and new members taken in against the vacant posts).
- A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- New members will be appointed if deemed necessary.

3.10 Resignation of a Member

- A member can resign by submitting a letter of resignation addressed to the Chairman and delivered to the Member Secretary; the same will be informed by the Secretary to the appointing authority for formal acceptance and to initiate necessary replacement/recruitment procedure for filling up the vacancy.
- The members if opt to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

3.11 Disqualification of Member

A member can be disqualified due to misconduct or continuous absenteeism from meetings without prior intimation as per the procedure laid down for the same.

3.12 Maintenance of records of IEC

- A list of members of the IEC-NIA, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the IEC-NIA.
- This list and the copy of the working procedures would be made available to any investigator, for the purpose of filing of research projects, upon written request for the same to the Chairman.

3.13 Hierarchy

- The Chairman will be the head of the committee.
- The Member Secretary will be the guardian of all documents and records of the committee.
- Other IEC members will be regular committee members with equal ranking.

3.14 Responsibilities of IEC-NIA

The main responsibility of IEC-NIA is to review and monitor all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants before approving the research proposals. It should ascertain that all the ethical principles of research such as Autonomy, Beneficence, Non-maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research.

IEC-NIA will review each study proposal for its both scientific and ethical review according to the standard guidelines as prescribed by Good Clinical Practice (GCP), Indian council of Medical Research (ICMR) guidelines and New Drugs and Clinical Trials Rules, 2019 and this SOP of IEC-NIA.

The responsibilities of IEC-NIA are:

- To protect the safety, dignity, rights and wellbeing of the potential research participants.
- To include solely those patients who have given informed consent for participation in the research.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To ensure equitable recruitment of subjects in the study.

- To ensure that the research is conducted under the supervision of the medical persons or scientists with required experience and expertise.
- To ensure that research work is going as per the approved protocol.
- To assist in the development and the education of a research community responsive to local health care requirements

3.15 Responsibilities of individual member:

- **Chairperson**

- Conduct EC meetings and ensure active participation of all members during the meeting
- Approve minutes of the previous meetings
- Seek conflict of Interest (COI) declaration from members and ensure quorum and fair decision making
- Handle complaints against researchers, EC members, conflict of interest issues, and requests for use of EC data, etc.

- **Member Secretary**

- Organize an effective and efficient procedure for receiving, preparing, circulating, and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication, and archiving
- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required and adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in the agenda for EC review
- Assess the need for expedited review/exemption from review or full review
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives
- Ensure quorum during the meeting and record discussions and decisions

- **Basic Scientist(s)**

- Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology, and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety, and pharmacodynamics in case of clinical trials

- **Clinician(s)**

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study, and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility, and appropriateness of the principal investigator, provision for medical care, management, and compensation

- Thorough review of protocol, investigator's brochure, and all other protocol details

- **Legal Expert**

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol-specific other permissions, compliance with guidelines, other legal issues associated with the research etc.

- **Social Scientist/Philosopher/Ethicist/Theologian**

- Ethical review of the proposal, ICD along with translations
- Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any
- Serve as a patient/participant/societal/community representative and bring in ethical and societal concerns

- **Layperson**

- Ethical review of the proposal, ICD along with translation(s)
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks
- Serve as a patient/participant/community representative and bring in ethical and societal concerns

3.16 Code of Conduct for IEC Members:

- Members are expected to show their full commitment and responsibility in the ethical review process.
- Members are expected to respect divergent opinions and maintain confidentiality.
- Members are expected to review proposals without bias and without any external influences.
- Members of IEC are expected to attend all IEC meetings.
- Prior information should be provided if a member is unable to attend a meeting.
- Members shall maintain the highest level of professionalism, integrity, and ethical standards.
- Members shall declare conflict of interest and recuse themselves from review process if necessary.
- Members shall respect the privacy and confidentiality of research participants and the research proposal.
- Members shall avoid bias and ensure impartiality in the review process.
- Members shall maintain the confidentiality of the review process and not disclose any information outside the committee.
- Members shall abide by the decisions of the committee and respect the opinions of fellow members.

- Members shall continuously update their knowledge and skills to ensure competence in the review process.

3.17 Independent Consultant/Invited Subject Experts

- The IEC may nominate Independent subject experts to assist in the review and provide an independent opinion.
- Their opinion will be valuable, but they will not be involved in the decision-making process.
- The IEC will nominate the name of one or more subject experts, endorsed by the Chairman, upon the advice IEC member(s).
- The IEC will designate subject experts from different specialties, and the Chairman/Member Secretary will invite the selected expert in writing to assist in the review and provide an independent opinion.
- Prior approval of the Vice chancellor, NIA will be essential to invite the expert.
- Subject experts will participate after agreeing to the confidentiality clause (Ax: 08-04) and abiding by IEC rules and regulations.
- Their opinion will be valuable, but they will not be involved in the decision-making process.
- The expert will be requested to provide a written opinion within 7 working days, depending on the gravity and seriousness of the matter.
- The Member Secretary will provide explanations/clarifications (telephonically or in writing) to the subject experts if doubts or questions arise.
- The Chairman, Legal Expert or other IEC members can provide further explanations if necessary.
- Subject experts may be reimbursed for expenses (travel, time spent, documents referred to in library/internet, incidental expenses, etc.) if deemed necessary

3.18 Fees related to ethics committee activities

- An administrative fee/processing fee of INR Twenty thousand only (Rs 20,000/) or 5% of their sanctioned budget (whichever is higher) will be charged for all research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals, etc.
- Waiver of these fees is permissible for non-funded studies, departmental studies, or other projects of national importance, subject to approval of the NIA authorities.

Method of Payment:

- All processing charges should be deposited in the bank account of Secretary, IEC. Account number 3643535161, IFSC code CBIN0283634, Central Bank of India, NIA Branch, Jaipur.

- Fee receipt can be collected from the accounts section of NIA on production of the transaction number and details.
- The committee review fee should be incorporated into budgets of the proposals

3.19 Expenditure from IEC Account:

The expenditure will be made from the IEC account towards:

- Paying Honorarium to members of IEC and invited experts.
- Training programs organized by IEC for its members.
- Arrangements for meetings, including stationery, food and other miscellaneous expenses.

3.20 Payment of Honorarium:

- Reimbursement of traveling expenses, honorarium for attending IEC meetings, and/or honoraria may be given to IEC members/office bearers/independent consultants
- Honorarium of INR 5,000/- per sitting will be paid by the IEC/Institute to the external members for attending the meeting.

3.21 Administration and management:

- NIA administration should provide an office for the IEC-NIA with adequate space, infrastructure and staff to maintain a full-time secretariat, safe archival of records, and conduct of meetings.

3.21.1 The Secretariat

- The Secretariat is composed of the Member Secretary, affiliated IEC members and one coordinator/staff. Coordinator of IEC will be appointed by the VC, NIA. who will coordinate with member secretary to foster the functioning of the secretariat.

3.21.2 The secretariat shall have the following functions

- Provision of necessary administrative support for IEC related activities to the
- Member Secretary, IEC
- Documentation of IEC activities including meetings, training, discussions etc in coordination with the member secretary
- Organization of an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files to the IEC Members
- Organization of regular IEC meetings
- Preparation of the agenda and the minutes of the meetings
- Maintenance of the IEC records and archives
- Communication with IEC members and PIs
- Arrangement of training for investigators and IEC members

3.22 Preparation of Annual activity report

The Member Secretary along with the secretariat and affiliated members in Consultation with the Chairperson, IEC shall prepare an annual activity report of the IEC for submission to the VC NIA and accreditation board. This shall include:

a. A quantitative evaluation of the activities of the committee in a year.

b. List of the research proposals reviewed in the report year.

POLICY FOR TRAINING OF IEC-NIA MEMBERS

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

4. POLICY FOR TRAINING OF IEC MEMBERS:

4.1 Purpose:

To ensure that all members of the Institutional Ethics Committee (IEC) are adequately trained and familiarized with guidelines related to research and ethics, to maintain the highest standards of ethical review and oversight.

4.2 Scope:

This policy applies to all members of the IEC, including the Chairman, Member Secretary, and members.

4.3 Responsibilities:

All IEC members must familiarize themselves with relevant guidelines, including:

- GCP Guidelines for ASU medicine (2013)
- ICMR National Ethical Guidelines (2017)
- New Drugs and Clinical Trials Rules (2019)

- Member-secretary or an IEC member will provide an introductory training to the new member.
- All IEC members must undergo a refresher course in Good Clinical Practice (GCP) in online or offline mode.
- The appointing authority will provide support and encouragement for members to attend such training programs.
- The SOPs will be updated periodically based on changing requirements, and members will be informed of any changes.

4.4 Training mode

- The Chairman, Member Secretary, and members are encouraged to attend training programs, conferences, workshops, seminars, and courses in research ethics to improve the quality of review and related activities.
- Training can be taken in both Online and offline mode from authentic and approved source/institutions

4.5 Training Requirements:

- IEC members must complete the required training within 6 months of appointment and every 2 years thereafter.
- Training programs must be approved by the appointing authority.
- Members must provide proof of completion of training to the Member Secretary.

4.6 Record Keeping of trainings:

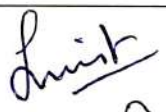
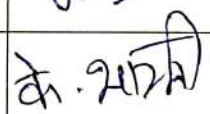
- The Member Secretary/secretariate will maintain records of member training, including dates, topics, and proof of completion.
- Records will be updated regularly and made available to the appointing authority upon request.

By implementing this policy, the IEC aims to ensure that its members are equipped with the knowledge and skills necessary to provide high-quality ethical review and oversight of research studies

POLICY FOR RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBERS OF IEC-NIA

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

5. PROCEDURE FOR RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBERS OF INSTITUTIONAL ETHICS COMMITTEE (IEC-NIA)

5.1 Purpose

To outline the procedures for addressing unauthorized absence and disqualification of Institutional Ethics Committee (IEC) members.

5.2 Scope:

This policy applies to all IEC members.

5.3 Procedure :

5.3.1 Resignation of a member

IEC-NIA members who decide to resign must provide the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting to the Vice chancellor, NIA.

The members who have resigned may be replaced at the discretion of the Vice chancellor, NIA.

5.3.2 Termination / Disqualification procedure

A member shall be relieved or terminated of his/her membership in case of -

- Conduct unbecoming for a member of the IEC-NIA.
- Inability to participate in the meetings on any grounds
- Failure to attend more than 3 consecutive meetings of the IEC and subsequent to review of the membership by the IEC.
- Relocation to another city or any such matter
- In all such situations/circumstances, Vice chancellor, NIA will serve a letter of termination to the member. Documentation of the termination will be recorded in the minutes of the next duly constituted IEC meeting and the IEC membership roster and circulars will be revised.

5.3.3 Replacement procedure

In case of resignation, VC, NIA would appoint a new member, falling in the same category of membership e.g. legal expert.

Similar procedure of appointment of new membership should be followed.

6. POLICY FOR PROTOCOL SUBMISSION AND ITS MANAGEMENT

6.1 Purpose:

This standard operating procedure is designed to describe how the Secretariat of the IEC manages protocol submissions to the IEC for review.

6.2 Scope:

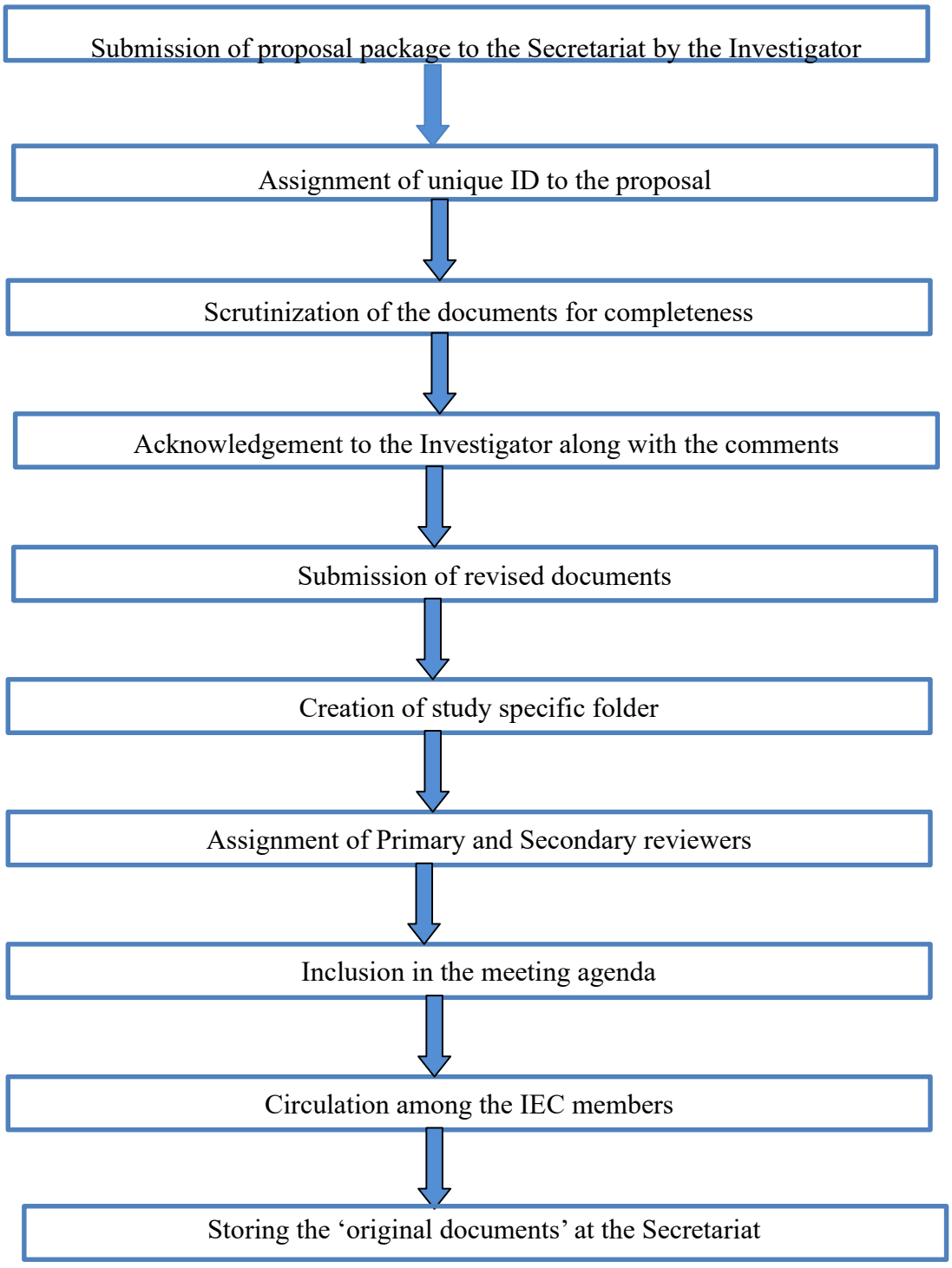
Protocol submissions include:

a. Initial review
b. Expedited review, including student/scholar research reviews.
c. Exemption from review
d. Amendment to the protocol
e. Continuing review of approved protocols
f. Protocol Termination
g. Study completion

6.3 Responsibility:

It is the responsibility of the IEC-NIA secretariat to receive record, and its distribution for review, as well as to deliver the review results to the protocol applicants.

6.4 Flow chart on Management of Protocol submission



6.5 Detailed instructions - For the secretariat staff :

- Receive submitted packages
- Check for submission items
  - Get relevant forms according to the category of submission.
  - IEC-NIA accepts only the completed submission
  - Check for index/Table of contents each provided in the protocol file.
- Provide filled in acknowledgement form to the PI/investigator
- Verify contents of Submitted Package as per the checklist
- Create a Protocol Specific File
- Assign unique project ID No. in the following format: NIA/IEC/yyyymm/XX, in which yyyy is year in four digits and mm is month in two digits and XX is unique serial number for the submitted protocol for reviewing by the IHEC meeting.
    - e.g. NIA/IEC/202308/01 refers to the protocol submitted to NIA-IEC in the year 2023 for reviewing in the meeting held on August and last two digits refers to the unique continuous number assigned to the particular protocol.

- Complete the submission process
  - Check for completeness of information in the submitted package. b. Notify the applicants if a package is incomplete.
  - State clearly the items missing in the package.
  - Fill up the related parts and the missing documents.
  - Stamp the receiving date on the letter and on the first page of the documents.
  - Initial of the receiver's name on the receiving documents.
  - Staple the filled checklist (according to the category of the protocol
  - submission) with the protocol submission cover letter.
  - File a copy of the document receipt form in the "***Protocol Receipt***" folder.
  - File a copy of the submitted documents with original signatures in the "Submission" Folder.

- Store the received packages

a. Bind the packages together appropriately.

b. Store the dated and initialled original protocol packages on the IEC submission shelf for review in sequence.

6.6 Detailed instruction - For investigators

6.6.1 Submission Guidelines

- Submit the proposal to the IEC at least 3 weeks before the scheduled meeting.
- Use the prescribed application form and include relevant documents.
- Proposal is to be submitted in hard as well as soft copy.
- Soft copy is to be submitted to email id- **iec.nia.edu.in**
- Proposals must be cleared by the Institutional Research Review Board (IRRB) of National Institute of Ayurveda before submission to the Ethical Committee.
- M.D/M.S./MSc and Ph.D. student proposals must be approved by the respective Departmental Research Committee (DRC) and Institutional Research Review Board (IRRB).

6.6.2 Application Requirements

- Submit 2 hard copies and a soft copy of the proposal, application, and documents in the prescribed format.
- Ensure that the Principal Investigator (PI) and Co-investigators/Collaborators have signed the applications.
- The PI should forward the application to the Chairperson, IEC, through the Member Secretary.
- The IEC office will acknowledge receipt of the application and assign an IEC acknowledgement number for future correspondence and reference.
- The PI will be informed of the IEC meeting date and required to attend and present the proposal.
- IEC may suggest online meetings and virtual presentations in special situations.

6.6.3 Documents to be submitted (checklist)

- Cover letter to the Member Secretary.
- Type of review requested.
- Application form for initial review.
- One page summary of the project proposal
- Complete protocol on the prescribed proforma.
- Approval of the project by IRRB- NIA.
- Informed consent document (ICD) in English and local language(s).
- Case record form/questionnaire.
- Recruitment procedures.
- Patient instruction/information brochure , diary, etc.
- Investigator's brochure (as applicable).
- Details of funding agency/sponsor and fund allocation (if applicable).

- Brief curriculum vitae of all study researchers.
- Statement on conflict of interest (COI), if any.
- GCP training certificate (preferably within 5 years) of investigators (sponsored clinical trials).
- Any other research ethics/other training evidence (if applicable).
- List of ongoing research studies undertaken by the principal investigator (other than PG/PhD thesis supervision works).
- Undertaking with signatures of investigators.
- Regulatory permissions (as applicable).
- Relevant administrative approvals.
- MoU in case of studies involving collaboration with other institutions (if applicable).
- Clinical trial agreement between the sponsors, investigator, and the head of the institution(s) (if applicable).
- Insurance policy (if applicable).

6.6.4 Contents of Protocol

The protocol should include the following important information:

- Title page with signatures of investigators.
- Background with rationale of why a human study is needed.
- Justification of inclusion/exclusion of vulnerable populations.
- Clear research objectives and endpoints/outcome.
- Eligibility criteria and participant recruitment procedures.
- Detailed description of the methodology of the proposed research.
- Duration of the study.
- Justification for use of placebo, benefit-risk assessment, plans to withdraw and rescue medication.
- Procedure for seeking and obtaining written informed consent.
- Plan for statistical analysis of the study.
- Plan to maintain privacy and confidentiality of study participants.
- For research involving more than minimal risk, an account of management of risk or injury.
- Proposed compensation, reimbursement of incidental expenses, and management of research-related injury/illness during and after research period and insurance policy.
- Provision of ancillary care for unrelated illness during the duration of research.
- An account of storage and maintenance of all data collected during the trial.
- Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/identity.
- Ethical considerations and safeguards for protection of participants.

7. CONVENTION AND CONDUCT OF IEC-NIA MEETINGS

7.1 **Purpose**: To ensure that meetings of the Ethical Committee of NIA are conducted in a fair, transparent, and efficient manner.

7.2 **Scope**: This SOP applies to all meetings of the Ethical Committee of NIA.

7.3 **Responsibilities**:

- Chairperson, Ethical Committee: Convenes meetings, sets agenda, and ensures quorum.
- Members, Ethical Committee: Attend meetings, review materials, and participate in discussions.
- Secretary, Ethical Committee: Records minutes, maintains records, and sends notifications.

7.4 Meeting Schedule and Convening a meeting

- The meeting of the IEC will be held every 4 months, unless otherwise specified by the Member Secretary in consultation with the chairman.
- Additional review meetings can also be held with short notice as and when required.
- Meetings will be planned in accordance with the need of the workload.
- Prior permission will be taken from Vice chancellor NIA to conduct meeting at NIA on the decided date.
- After consultation with the Chairman and Members and permission of the Vice chancellor NIA, the Member Secretary will provide information for the upcoming Ethical Committee meeting via an office order approximately 15 days in advance.
- All proposals will be received at least 3 weeks before the meeting, and after initial scrutiny by the Member Secretary, the proposals will be circulated to the IEC members.

7.5 IEC- NIA Meeting Agenda

- The Ethical Committee will have an agenda for each of its meetings.
- The agenda will include listing and identifiers for all research project applications awaiting action by the Ethical Committee.
- At least seven days in advance of the scheduled meeting date, the agenda will be made available by email or post for review by members of the Ethical Committee.
- All documents relating to a study submitted by an investigator will be distributed as electronic/paper copies and sent to the members of the Ethical Committee scheduled to conduct the full review.

7.6 IEC- NIA Meeting Procedures

- Except when an expedited review procedure is used, the Ethical Committee will review proposed research at convened meetings at which a majority of the members of the Ethical Committee are present, including at least one member whose primary concerns are in non-scientific areas.
- The Chairperson will conduct all meetings of the IEC-NIA. In the absence of the Chairperson, an alternate Chairperson will be elected from the other members on the day of the meeting (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the members present, who will conduct the meeting.
- The alternate or acting Chairperson should have the powers of the Chairperson and should be a non-affiliated person.
- The Member Secretary is responsible for organizing the meetings, maintaining the records, and communicating with all concerned.
- The PI/Research Scholar will present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons, the Co-PI will be allowed to present the proposal. Researchers will be invited to offer clarifications on a case-to-case basis, if needed.
- Decisions will be taken by consensus after discussion, and whenever needed, voting will be done.
- The review discussions/decisions will be charted down, and the final minutes will be approved by the Chairperson.
- After the IEC meeting, the decision of the IEC members regarding the discussed proposals will be obtained on the same day of the meeting.
- Member Secretary will prepare the minutes of the meetings and get them approved by the Chairperson and all the members.
- In the absence of the Member Secretary, an alternate Member Secretary among the members will organize the IEC meeting.

7.7 Declaration of Conflict of Interest

- Members are expected to declare conflicts of interest, if any, before the commencement of the meeting.
- IEC members should not take part in discussion or decision-making on research proposals in which they are PI or Co-investigators or if there are any other conflicts of interest.
- Member may leave the site of the Ethical Committee meeting for the duration of the review of that application.
- If the member with a conflict of interest is present, they will only provide required study-related information and will not be a part of the decision-making process.

7.8 Ethical Committee Meeting Minutes

- The Secretary of the Ethical Committee will prepare minutes of each meeting of the Ethical Committee, during which research projects are being reviewed.
- The minutes will be in sufficient detail and will include the following:
    - Date and venue of the meeting
    - Attendance of members and reason for absence of primary members. If primary members are absent, the presence of alternate members
    - Decisions reached on each research project application reviewed
    - If a condition arises, distribution of membership votes on the decisions, documenting the number of votes for, against, and abstaining
    - Reasons for requiring changes in a project or disapproving, suspending, or terminating a project
    - If vulnerable groups of subjects were included in the research, the justification for their inclusion, and adequacy of special precautions taken to minimize risks
    - Summary of the discussion of disputed issues and their resolution
    - Date of the next scheduled continuing review of a project
- The minutes will be made available for review to the Ethical Committee members by email and/or post.

8. REVIEW PROCEDURES TO BE FOLLOWED BY IEC -NIA

8.1 **Purpose**

- Every research study involving human participants and other forms of studies, before the research is initiated should be reviewed and approved by the IEC. The IEC should evaluate the ethical aspects of the study, which had already approved by the Institutional research review board (IRRB), other scientific bodies such as ICMR-Task Force/ DST/DBT/CCRAS or others. However, the IEC may also look into the ethical aspects involved in the methodology. The committee should evaluate the possible risks to the participants with proper justification as well as the expected benefits to participants/community. The adequacy of documentation for ensuring privacy & confidentiality should also be reviewed. The purpose of this Standard Operating Procedure (SOP) is to describe how the IHEC members will review an initial submission of the research study for approval.

8.2 **Scope**

- This SOP applies to the review of all studies submitted for IHEC review and approval of the
- IEC. The specific points/items in the Reviewers Form must be adequately addressed in the protocol and/or protocol-related documents submitted for the review. Relevant comments made during discussion and deliberation about a study should be recorded in the minutes of the meeting. The decision reached by the IEC will be communicated to the PI.

8.3 Responsibility

- The IEC Secretariat is responsible for receiving, verifying, and managing the hard/soft copies of the received submission. In addition, the Secretariat should create a study specific file, distribute the packages and study assessment forms to the IEC members for review, and communicate the review results to the investigators.

8.4 Type of Review

The Member-Secretary, with the support of the coordinating/support staff, shall screen the proposals for their completeness and depending on the risk involved, categorize them into three types, namely:

- Exemption from review

- Expedited review
- Full committee review

8.4.1 Exemption from Review

- Proposals that present "less than minimal risk" fall under this category.
    - Probability of harm or discomfort anticipated in the research is nil or not expected.
    - Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.

8.4.2 Expedited Review

- The Member-Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve:
- "no more than minimal risk" to research participants may be subjected to expedited review.
    - Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where the occurrence of serious harm or an adverse event (AE) is unlikely.
    - Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
    - Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
    - Clinical trials involving Ayurvedic medicines mentioned in 56 authoritative texts in same dosage, dosage form and indication.

- Minor deviations from originally approved research protocol during the period of approval.
- Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
- When in emergency situations like serious outbreaks or disasters, a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention, and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.
- Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

8.4.3 Full Review

- All research presenting with "more than minimal risk", proposals/protocols which do not qualify for exempted or expedited review,
- Research involving vulnerable populations, even if the risk is minimal.
- Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse or modify any decision taken by the subcommittee or expedited committee.
- Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms, etc.) involving an altered risk.
- Major deviations and violations in the protocol.
- Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit-risk assessment.

8.5 Review of Informed consent process

- The informed consent document (ICD), including patient/participant information sheet (PIS) and informed consent form (ICF), should be reviewed for all the required elements as per ICMR Guidelines 2017.
- For all biomedical and health research involving human participants, it is the primary responsibility of the researcher to obtain the written, informed consent of the prospective participant or legally acceptable/authorized representative (LAR) or the nominated representative typically parents/guardians or state-appointed persons in all aspects of decision-making of minors. In case of an individual who is not capable of giving informed consent, the consent of the LAR should be obtained. If a participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process.

8.5.1 Waiver of Written Informed Consent

- The IEC may grant a waiver for the requirement of obtaining written informed consent for requesting waiver of consent by the investigators. The Chairman/Member Secretary/IEC members will review the request, taking into consideration the types of studies for which waiver of consent may be granted. The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data. This is necessary, as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process when consent waiver is granted.

8.5.2 Guidelines for Participant Information Sheet and Informed Consent Form

Participant information sheet

- While the guidelines for participant information sheet (PIS) contain several items, only those applicable or relevant to a particular study should be included in the documents of that study.
- The PIS is meant for persons who are prospective participants in a study or their guardians/legal representatives. It is meant for them to understand the study, their role in it if they participate, the risks and benefits, possible side effects, the implications of blinding and randomization, etc., in order that they can make an informed decision whether to participate or not. Sample size, inclusion & exclusion criteria in technical terms are not relevant for this purpose.
- The study protocol, in technical language, should not be cut and pasted on to the PIS. The PIS should be in simple language that a layperson can understand. English and vernacular versions of the PIS should be prepared.
- As the information is being conveyed by the Investigator/ study personnel, they should explain to the participant 'why you should participate in this study' rather than 'why I should participate'?
- The prospective participant should be explained the possible risks and complications, even if the chances of such risks /complications are low.
- The prospective participant should be told that they have the right to NOT participate or to with draw at any time in case of most studies. However, the time up to which such withdrawal is possible should be explained, according to the nature of the study.
- Financial terms such as Incentives, Inducements, Reimbursement and Compensation should be properly understood by the Investigator and conveyed appropriately to the prospective participant.
- The prospective participant should be explained about potential benefits directly to him /her and /or to scientific advancement and / or to society at large, according to the nature of the study.
- The prospective participant should be explained the procedures for maintaining confidentiality of (a) Identity of participant, (especially if photographs are to be taken and published), and (b) personal data.
- The prospective participant should be told that any outcome of investigations performed as part of the study will be conveyed to him /her automatically.
- If relevant, the prospective participant should be explained the circumstances under which a study could be terminated prematurely (as may happen in clinical trials).
- It is not necessary to state in the PIS that 'the study has been reviewed and approved by the Ethics Committee'.
- In case the investigators themselves are not conversant with the local language, the person who will administer the PIS / convey the information, and seek consent should be identified.

- The PIS should carry the name of the principal investigator along with Contact Information. In case of item 13 mentioned above, the contact information of the person giving the information on the study should also be stated on the PIS.
- For the purpose of protecting the rights of the participants /for complaining against unethical practices in carrying out the project /for clarification of queries related to ethical conduct of the project, the contact information of the Chairperson, IHEC should be given along with the telephone number of the IHEC Secretariat.
- The PIS for Healthy Volunteers or Healthy Controls has to be different from that of prospective participants who have illnesses, as the purpose of their personal benefit in anyway. This has to be explained clearly.
- One Copy of the PIS should be given to the prospective participants.
- There is no need for the prospective participant or guardian or a witness to sign on the PIS.

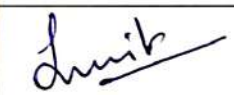
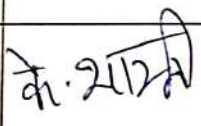
Consent form (CF)

- Consent form should be in English and the local language.
- The content and wording of the CF should be relevant and appropriate for prospective participants/ guardians, for the study in question, and should be customized suitably.
- The CF for Healthy Volunteers and Healthy controls should also be suitably customized.
- 'Denial of consent' document should NOT be asked for, and no signatures attesting to refusal to participate or with drawl of consent should be sought.
- CF should be signed by the participant (or legal guardian where applicable). It should also be signed by a Witness, who should be from the participant's side (and not from hospital staff or those associated with the project/ study. The person obtaining the consent should also sign the CF with name, designation and date). If the prospective participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure. This should be properly documented by the Investigator/Interviewer by getting signature from the prospective participant.
- One copy of the CF, duly signed as above, should be given to the participant/ guardian. Original should be retained as part of the Study Records by the Investigator and produced if required at any time

POLICY TO PREVENT CONFLICT OF INTEREST

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

9. **POLICY TO PREVENT CONFLICT OF INTEREST**

The Institutional Ethics Committee (IEC) recognizes that conflicts of interest may arise, but trusts in its ability to manage them to ensure the protection of human subjects. To achieve this, IEC members must disclose any potential conflicts of interest and abstain from participating in reviews where a conflict exists.

9.1 Purpose: To ensure the protection of human subjects by managing conflicts of interest among Institutional Ethics Committee (IEC) members.

9.2 Scope: This policy applies to all IEC-NIA members and research studies reviewed by the committee.

9.3 Procedures

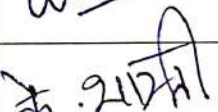
- Every IEC-NIA member must sign a conflict of interest agreement and maintain confidentiality before participating in ethical reviews.
- Members must disclose potential conflicts of interest in writing, including those related to family members or professional associates, when submitting proposals.
- Disclosures must be detailed and timely to allow for appropriate management of conflicts by the IEC-NIA administration.
- Investigators who are also IEC-NIA members cannot participate in reviews or approvals of projects they are involved in.
- At each meeting, the Chairperson or Member-Secretary will ask members to declare any conflicts of interest related to the agenda items.
- The Chairperson or Member-Secretary will review disclosures and determine appropriate management of conflicts.
- Members with conflicts of interest will abstain from discussions and decision-making, except to provide requested information.
- Abstentions due to conflicts of interest will be documented in the minutes.
- If a conflict affects quorum, the proposal will be deferred to the next meeting.
- If the Member-Secretary has a conflict of interest, he will declare it and leave the meeting room, and another member will assume the role of Acting Member Secretary.
- The Acting Member Secretary will manage any queries related to the project during lifetime of the project.
- Minutes will clearly indicate projects where the Member Secretary had a conflict of interest and did not participate in decision-making

POLICY FOR REVIEW OF RESEARCH PROPOSALS

INVOLVING VULNERABLE POPULATION

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

10. POLICY FOR REVIEW OF RESEARCH PROPOSALS INVOLVING VULNERABLE POPULATION

10.1 Purpose:

To ensure the protection of vulnerable populations in research studies reviewed by the Institutional Ethics Committee (IEC) of the National Institute of Ayurveda (NIA).

10.2 Scope:

This policy applies to all research studies involving vulnerable populations reviewed by the IEC-NIA.

10.3 Definition and inclusions

Vulnerable populations in research refer to individuals or groups who are at a higher risk of being exploited, harmed, or unable to provide informed consent due to various factors. These factors may include:

- Limited understanding or capacity to provide informed consent (e.g., cognitive impairment, mental illness, or language barriers).
- Dependence on others for care or support (e.g., children, prisoners, or individuals with disabilities).
- Social or economic disadvantage (e.g., poverty, homelessness, or minority status).
- Limited access to resources, education, or healthcare.
- Power imbalance (e.g., researcher-participant relationship, authority figures, or unequal status).
- Special considerations would be taken while reviewing projects involving research on vulnerable populations, including:
    - Pregnant women
    - Children (up to 18 years)
    - Economically disadvantaged
    - Sexual minorities
    - Terminally ill
    - Suffering from mental, stigmatizing, or rare diseases
    - Tribals and marginalized communities
    - Differently abled - mentally and physically disabled
    - Having diminished autonomy due to dependency

10.4 Responsibilities of the researcher:

Identification: The researcher must identify vulnerable populations in the study protocol and provide justification for their inclusion.

Risk-Benefit Assessment: The researcher must conduct a thorough risk-benefit assessment to ensure that the potential benefits of the study outweigh the risks for vulnerable populations.

Additional Safeguards: The researcher must implement additional safeguards to protect vulnerable populations, such as obtaining informed consent from a legally authorized representative, using anonymous coding to protect participant identities, and providing adequate support and resources.

10.5 Procedure for review

IEC Review: The IEC-NIA will review the study protocol and risk-benefit assessment to ensure that the rights and welfare of vulnerable populations are protected.

Only the full Committee does initial and continuing review of such proposals. Empowered representatives from specific populations are included during deliberations, if possible.

Monitoring: The IEC-NIA will monitor the study to ensure compliance with the approved protocol and safeguards.

10.6 Policy on Research Involving Institutional Students or Staff

The IEC does not allow the use of trainees/employees as trial participants unless:

- Students and staff have the same rights as other potential subjects.
- No competitive academic or occupational advantage is given to participating Institutional subjects.
- No academic or occupational penalty is imposed on those who do not volunteer.
- Institutional students and staff are not systematically treated differently from non-Institutional subjects.

Head of the Institution/Head of Department reviews participation of Institutional students and staff, especially those under the direct supervision of the PI or listed research collaborators.

POLICY ON MULTICENTRIC RESEARCH

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

11. POLICY ON MULTICENTRIC RESEARCH

11.1 Multicentric research is conducted at more than one centre by different researchers, usually following a common protocol.

- All sites are required to obtain approval from their respective Ethics Committees (ECs), which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety, and well-being of the participants.
- The ECs/Secretariats of all participating sites should establish communication with one another.
- If any EC does not grant approval for a study at a site, the reasons must be shared with other ECs and deliberated upon.
- The EC can suggest site-specific protocols and informed consent modifications as per local needs.

- Separate review may be requested for studies with a higher degree of risk, clinical trials, or intervention studies where conduct may vary depending on the site or any other reason that requires closer review and attention.

11.2 Common Review for All Participating Sites in Multicentric Research:

- To save time, prevent duplication of effort, and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
- IEC -NIA may perform expedited review based on decision of above common review.
- Common review process may be applied to research involving low or minimal risk, surveys, or multicentric studies using anonymized samples or data, or those that are public health research studies determined to have low or minimal risk.
- The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, the local participating sites would be required to obtain local ethical approval.

12. DECISION-MAKING & COMMUNICATION OF DECISION

12.1 Process of decision making

- Members will discuss various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
- A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and convey this to the Chairperson prior to the review of the application, which will be recorded in the minutes.
- Decisions will be made only in meetings where a quorum is complete.
- Only members can make decisions. Expert consultants (subject experts) will only offer their opinions.
- Decisions may be to approve, reject, or revise proposals. Specific suggestions for modifications and reasons for rejection will be given.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
- If revisions are required, the revised proposal must be submitted within the stipulated time period or before the next meeting.
- Modified proposals will be reviewed by an expedited review through identified members.

12.2 Communication of Decision

- Decisions taken on proposals will be communicated by the Member Secretary/Secretariat in writing to the PI/Research Scholar within two weeks after the meeting at which the decision was taken in the specified format.
- In case of Research where the Principal Investigator (PI) happens to be the Member-Secretary of IEC-NIA, the decisions of IEC-NIA shall be signed/counter signed by the Chairperson IEC-NIA or a co-convener or a member designated for this purpose.
- IEC approval will be valid for two years or for the duration of the project, whichever is less. The investigator must get their project re-approved after two years, where required. For PG/PhD thesis proposals, IEC approval will be valid for the duration of the project.

12.3 **Contents of the communication of Decision**:

- Name and address of IEC
- IEC communication number
- Date of the decision
- Name and designation of the applicant
- Title of the research proposal reviewed
- Clear identification of protocol no., version no., date; amendment no., date
- List of EC members who attended the meeting
- A clear statement of the decision reached
- In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed
- In case of rejection of the proposal, reason(s) for rejection will be clearly stated
- Signature of the Member Secretary with date

POLICY ON REVIEW OF ONGOING RESEARCH PROJECTS

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

13. POLICY ON REVIEW OF ONGOING RESEARCH PROJECTS

13.1 Purpose

The purpose of continuing review is to monitor the progress of the study, which was previously approved; not only for the changes but to ensure continued protection of the rights and welfare of research participants.

13.2 Scope

This SOP applies to conducting continuing review of research studies at intervals

appropriate to the degree of risk but not less than once a year.

Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, IEC may choose to review the study more frequently.

13.3 Responsibility

It is the responsibility of the IEC Secretariat to send reminders to PIs regarding the submission of Continuing Review Application/Annual Status Report.

All the approved studies will be reviewed annually. The IEC is responsible for

determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IEC meeting wherein the project is finally approved and the same should be clearly mentioned in the decision letter issued to the investigator Clinical trials under the purview of a licensing authority must comply with all regulations applicable to SAEs.

IEC is responsible for reviewing the study progress, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate.

The IEC has the same options for decision making on a continuing review

application as for an initial review application. The decision is made as, approval to continue the study; revision or disapproval

Researchers should submit annual report to the IEC-NIA in a timely manner including:

- Amendments to the project and protocol
- Protocol violations/deviations
- Serious Adverse Event (SAE) reports

- If a study is prematurely terminated, suspended, or discontinued, the researcher should inform the IEC as per the format .
- These reports are reviewed by a designated IEC-NIA member, and any discrepancies noted in the work done with reference to the approved protocol are brought to the notice of the

full committee. Failure to submit timely progress reports to the IEC-NIA may result in the project being considered for withdrawal of approval without further communication.

13.4 Review of protocol deviation/non-compliance/violation

- IEC will check for deviation/non-compliance/violation of approved projects.
- Protocol deviation is defined as not following or implementing some aspect of the approved protocol by the investigator.
- The Member Secretary/Chairman will categorize protocol deviation as minor or major and may designate members to review and take a decision depending on the seriousness of the deviation/non-compliance/violation.
- Any change, divergence, or departure from the study design or procedures of the protocol that does not have a major impact on the subject's rights, safety, or well-being, or completeness, accuracy, study outcome, and reliability of study data, and has not been approved by IEC, will be considered a minor deviation.
- Deviation from the protocol approved by IEC that may affect the subject's rights, safety, or well-being, and/or completeness, accuracy, study outcome, and reliability of study data will be considered a major deviation.
- The PI should submit the protocol deviation report as per the format (Ax: 14-04).

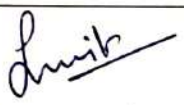
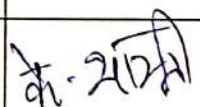
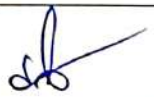
13.5 Review of Protocol Amendments

- In any occasion of amendments to the already approved protocol by IEC, the said amendment is reviewed by IEC in the next meeting following submission.
- The content of the amendment is critically reviewed with justification from an ethics point of view, following Good Clinical Practice (GCP) guidelines.
- Consensus approval from the committee members regarding this is recorded and communicated to the Principal Investigator.

POLICY ON REPORTING SERIOUS ADVERSE EVENTS (SAE'S)

DATE OF IMPLEMENTATION: 1st August 2024

VERSION NUMBER: 03

	Name	Designation	Signature
Prepared By	Dr Sumit Nathani	Mb Secretary, IEC-NIA NIA, Jaipur	
Reviewed By	Prof Bharati Kumarmangalam	Mb Secretary IRRB, NIA, Jaipur	
Approved By	Prof Sanjeev Sharma	Vice Chancellor NIA, Jaipur	

14. POLICY ON REPORTING SERIOUS ADVERSE EVENTS (SAEs)

14.1 Purpose

The purpose of this SOP is to provide instructions on reporting of Serious Adverse Events (SAEs)/Adverse Events (AEs) and review of SAEs/AEs reports submitted for any active study approved by the IEC-NIA.

Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the IEC to ensure adequate protection of the welfare of the study participants.

The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of subjects in the study.

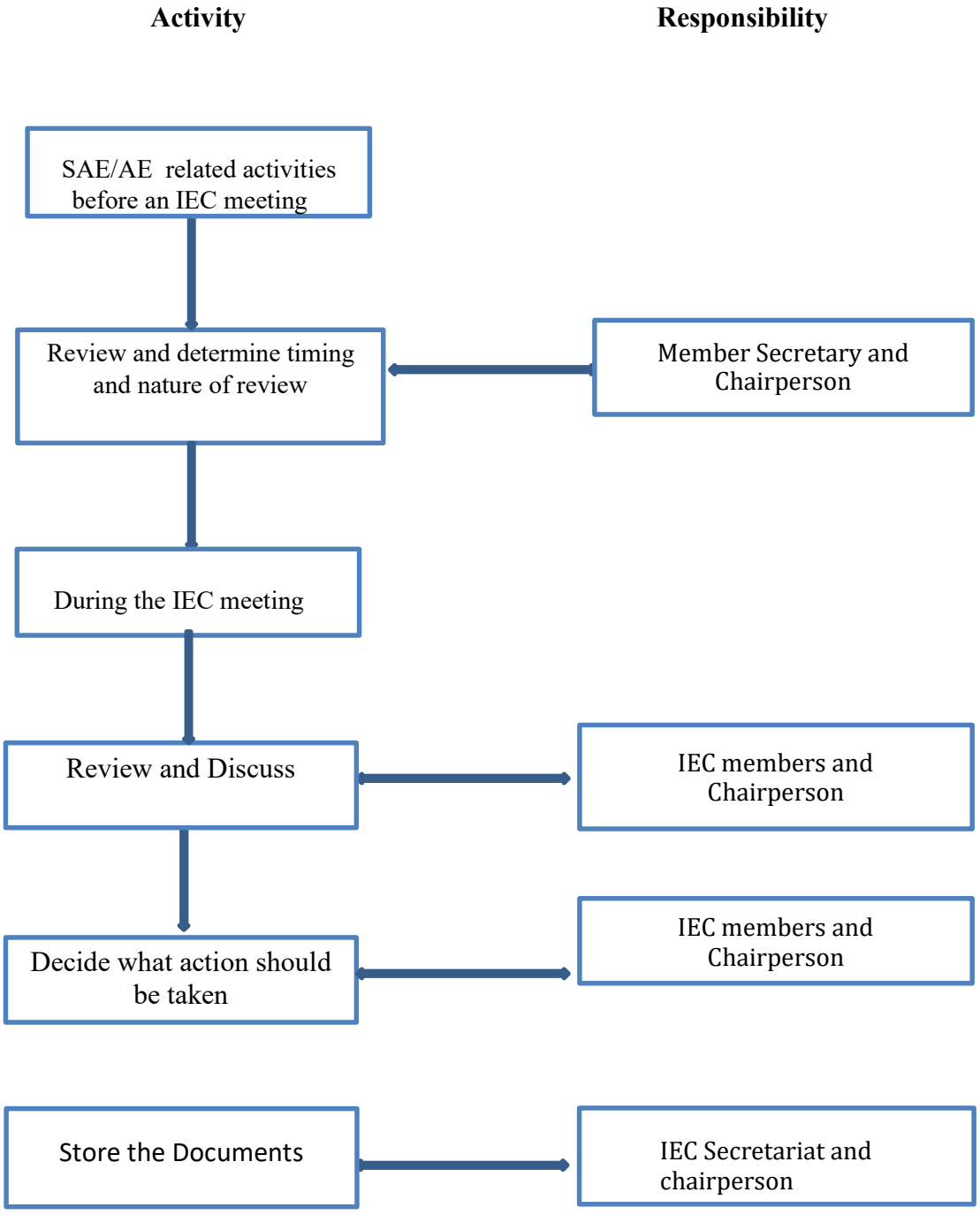
14.2 Scope

This SOP applies to the reporting of SAE/AE and review of SAE/AE reports submitted by investigators, sponsor, local safety monitor, IEC/IRB members or other concerned stakeholders.

14.3 Responsibility

- The Principal Investigator should communicate the SAE/AE to the IEC Secretariat within 24hrs on knowing about the SAE/AE. The communication can be done through email to IEC Secretariat.
- A detailed report on the SAE in the prescribed format must be submitted by the Principal Investigator within 14 days.
- Member Secretary and the Chairperson will screen the report and decide on the timing and nature of the reviewing the SAE/AE report
- IEC will review the relatedness of SAE/AE to research, management of the SAE/AE by the PI and decide on the quantum and type of assistance for the participant. The nature of the assistance can be decided based on the the type of research (interventional, observational, etc.), extent of injury (temporary/permanent, short/long term), loss of wages, etc
- Post review IEC will decide on the follow up of the SAE/AE
- IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

14.4 Flow Chart



14.5 Detailed instructions:

- The investigator must report all SAEs, including hospitalization or prolongation of hospitalization, clinical trial-related injury or death, regardless of causal relationship, to the EC within 24 hours of knowledge.
- Reporting of SAEs may be done through email (including on non-working days).
- A report on how the SAE was related to the research must also be submitted within 14 days.
- SAEs must be reported for all trials, and if applicable, timelines as specified by regulators must be followed (within 24 hours to the sponsor, EC, and regulator, if applicable, followed by a detailed analysis report in 14 days).
- The timeline for reporting SAEs should be as per ICMR Guidelines 2017, Drugs and Cosmetics Act 1940, Drugs and Cosmetics Rules 1945 (including amendments), and New Drugs and Clinical Trials Act and Rules 2019, as amended from time to time.
- The IEC shall forward the report on any SAE (including death), after due analysis, along with its opinion on financial compensation, if any, to be paid by the sponsor or representative, to the Chairman of the Expert Committee constituted by the Licensing Authority.
- A copy of the report must be submitted to the Licensing Authority within 21 calendar days of the occurrence of the SAE.

15. SUBMISSION OF PROJECT COMPLETION REPORT

- Researchers must submit a completion report of the project to the IEC-NIA in a timely manner.

- The work report is reviewed by a designated IEC-NIA member, and any discrepancies noted in the work done with reference to the approved protocol are brought to the notice of the full committee, which may merit immediate withdrawal of approval.

- Failure to submit a timely completion report to the IEC-NIA would make the project liable to be considered for withdrawal of approval without further communication.

16. RECORD KEEPING AND ARCHIVING OF DOCUMENTS

- All research proposals (hard copies along with soft copies) along with the information and documents submitted will be dated and filed.

- Documents will be archived for a minimum period of 3 years and for sponsored clinical trials, for 5 years after completion/termination of the study.

- IEC members should not retain any documents with them after the meeting is over.

List of Documents to be Filed and Archived:

- Constitution of IEC
- Terms of reference and SOPs
- CV & consent of IEC members
- Training certificates of the members of IEC committee
- IEC Registration
- Honorarium details, Income, and expenses (details to be maintained by Accounts section of the Institute)
- Agenda & minutes of meetings
- One copy of proposal
- Copy of recommendations/decision communicated to applicant
- Review reports, documents received during the follow-up period, and final reports of the study
- Amendments / Deviations / SAEs reported in relevant forms

FORMS

FOR IEC-NIA MEMBERS

AND OFFICE STAFF

(Annexures A- G)

Annexure A

ACCEPTANCE LETTER BY MEMBER

To

The Vice Chancellor,

National Institute of Ayurveda (Deemed to be university) Amer Road, Jaipur

Sub: Consent to be a member of Institutional Ethics Committee (Human Studies)- Reg. Letter dated: ……

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC-NIA, Jaipur. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I here with enclose my latest CV with date and signature. Thanking you,

Yours sincerely,

Name: ……

Mb No ……

Email address ……..

Date

Annexure B

CONFIDENTIALITY AGREEMENT FOR MEMBERS OF IEC-NIA

I, ……. hereby do confirm that to maintain the integrity and sanctity in the best interests of the committee. I must volunteer to inform the chairperson/ Secretary and other members to withdraw myself from participating in any process that might lead to possible personal benefit owing to my presence as an opining and decision making member of the IEC during any of the meetings of the IEC in order to avoid the conflict of interest involved. I also do hereby declare that I will not breach the confidentiality and all the information that is accessible to me as a member of IEC, especially during the reviewing, decision making and any discussion, shall not be disclosed by me to anyone other than the members of the committee or concerned study related personnel, as approved by the regulatory body.

Signature:

Name & Designation:

Date:

Annexure C

DECLARATION OF CONFLICT OF INTEREST

I, ……., have following proposal(s) with the undersigned as Principal Investigator/Co-investigator or real/potential/perceived competing research program under review by the IEC IHBAS. I shall abstain from any participation in discussions or recommendations in respect of the proposal.

I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

Agenda No. Research Proposal No. Research Proposal Title

Signature

Name

Date

Annexure D

CONFIDENTIALITY AGREEMENT FORM FOR SUBJECT EXPERTS

I,_____ (Name and Designation) as a non- member of Institutional Ethics Committee National Institute of Ayurveda (IEC-NIA), understand that the copy/ copies given to me by the IEC, is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the chairman IEC-NIA. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Signature of the Subject expert

Date

Signature Chairperson of IEC

Date

Annexure E

CURRICULUM VITAE OF MEMBERS OF IEC-NIA

1. **Name:**
2. **Address (full work address):**
3. **Telephone number:** **E-mail-ID:**
4. **Present affiliation (Job title, department, and organization):**
5. **Affiliation with host institute: Yes/No**
6. **Qualification (starting from basic, add additional rows if needed):**

COURSES/ SUBJECT	INSTITUTE/ ORGANIZATION	YEAR

7. **Previous and other affiliations (add additional rows if needed):**

AFFILIATION	DESIGNATION	DURATION

8. **Role in proposed Ethics Committee (also add dual Role if any):**
9. **Suitability of the member in the assigned role, Elaborate (less than 100 words):**
10. **Previous EC experience: YES/NO, if yes add role/ duration with name of EC:**
    (previous EC experienceis mandatory for the Chairperson):

NAME OF ETHICS COMMITTEE	DESIGNATION/ ROLE	DURATION	
		FROM	TO

11. **Relevant research training/experience in the area: (add additional rows if needed):**

NAME OF ETHICS COURSE/ TRAINING	ORGANIZED BY	DATE	DURATION OF TIMIMG	ATTACH AGENDA/ TOPICS COVERED

12. **Relevant publications (any 5) and additional information (if any):**

**I hereby declare that, I do not have any Personal, Professional and Financial Conflict of Interest in executing the functions as an Ethics Committee member. In case of COI, it may be declared (Please enclose/ merge along with Bio-data).*

**I hereby acknowledge that I am trained/ will get trained within 6 months in ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, GCP Guidelines (if applicable), New Drugs and Clinical Trials (NDCT) Rules, 2019, EC Functions & SOPs and relevant regulations of the country (if trained certificate enclosed/ merged with Bio-Data.*

Signature: **Date:**

Annexure F

DOCUMENT RECEIPT FORM

Protocol Number:		**Submitted date:**	
Type of Submission	□Initial Review □Protocol Amendments □Expedited review □ Exemption from review	□Continuing Review of Approved Protocols □Protocol Termination □Study Completion □ ~~student/scholar research review~~	
Protocol Title:			
Principal Investigator:			
Designation:			
Documents submitted:	□Complete		
	Check what documents to be received later on.		
Documents to be submitted later: **Received by:**	□Information for subjects □Informed consent form □Case report forms (CRF) □Study budget □Investigator's brochure □Others……		
Date received:			

Note: *Please bring this receipt with you when contacting the IHEC Secretariat*

Annexure G

REVIEWERS' FORM

Comments of the Reviewer Member

(For attachment to the copy of the proposal to be sent to primary/secondary reviewer)

Name of the Member (reviewer): To be written by the Reviewer

***Project ID No:** To be assigned by the IHEC Secretariat

***Proposal title: To** be written by the Investigator

***Investigator(s):** To be written by the Investigator

1 **Review of competence of the investigator**

a.	Competence of the investigator	**Yes**	**No**
b.	Conflict of interest of the investigator *Comments (if any.)* _____ _____	**Yes**	**No**
c.	Whether the investigator's capability, availability of infrastructure and scientific environment to conduct the study within the time frame, described appropriately? *Comments (if any.)* _____ _____ _____	**Yes**	**No**

2.	**Review of scientific content**	**Yes**	**No**	**NA**
a	Is the project original and innovative? *Comments (if any.)* _____ _____	**Yes**	**No**	**NA**
b	Is this an attempt to validate, prove or disapprove the validity of existing knowledge? *Comments (if any.)*_____ _____ _____	**Yes**	**No**	**NA**
c	Does the project have appropriate study design, work plan and structure to achieve the stated objectives? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**

d	Does the proposal describe the relevance of the work in the context of contemporary translation or clinical research? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
e	The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants are appropriately described? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
f	Whether appropriate justification for the use of control arms given in the proposal? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
g	Whether the potential of the work that would be conducted to lead into a larger and high impact study has been described? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
h	Whether the criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole described appropriately? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
i	Whether the provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board are adequate? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
j	Whether the policy on study reporting and publication of the research described? *Comments (if any.)* _____ _____	**Yes**	**No**	**N**

_____

3. **Review of ethical issues**

a Risks of participation in the study for the participants

i. Individual

Yes **No**

Comments (if any.)

_____
_____
_

ii. Societal / Community

Yes **No**

Comments (if any.)

_____
_____
_

iii. Is the overall risk/benefit ratio

Acceptable Unacceptable

Comments (if any.)

_____

b Benefits

i. Direct

Reasonable Undue None

Comments (if any.)

_____
_____

ii. Indirect

Improvement in science/ knowledge Any other

Comments (if any.)

_____
_____

c Subject selection

i. Are Inclusion / exclusion criteria appropriate?

Yes No

Comments (if any.)

_____
_____

ii. Vulnerable subjects (women, child, mentally challenged, seriously or terminally ill, foetus, economically or socially backward and healthy volunteers) adequately protected?

Yes No NA

Comments (if any.)

_____
_____

iii. Adequate protection for special group of participants, if involved — Yes / No / NA

Comments (if any.)

_____

_____

d Is description of measures to protect privacy & confidentiality adequate? — Yes / No

Comments (if any.)

_____

_____

4 **Review of informed consent related issues**

a Participant information sheet — Adequate / Inadequate

b Consent form components addressed adequately? — Yes / No

If not please explain

_____

c Reimbursement, (if applicable) addressed adequately? — Yes / No

Comments (if any.)

_____

_

_____

_

d Is any reimbursement proposed for incidental expenses in participation? — Yes / No

If yes,

Appropriate / Inappropriate

If inappropriate, please comment

_____

_____

Recommendation of review — Please tick one

Approval ☐

Minor Revision ☐

Major Revision ☐

Disapproval ☐

Any other remarks / suggestions:

Reviewer's name

Signature and date

FORMS FOR INVESTIGATORS

(Annexures 1-11)

National Institute of Ayurveda
Deemed University (De-Novo)
Application Form for Initial Review

General Instructions: a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: ……

(b) Name of Ethics Committee: ……

(c) Name of Principal Investigator: ……

(d) Department/Division:……(e) Date of submission: dd mm yy

(f) Type of review requested[1]:

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: ……

……

……

(h) Protocol number (If any): …… Version number: ……

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission ii) Co-Investigator at time of submission:

…… ……

(k) Duration of the study: ……

[1] *Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*

[2] *Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: ………………………………………………………………………………………………… At site………………………………… In India……………………………… Globally ………………………………………

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

………

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): ……………………………………………………………………………………

………

………

………

………

………

………

………

………

………

………

………

………

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/	☐	Case Control	☐
Prospective	☐	Public Health		Cohort	☐
Qualitative	☐	Socio-behavioral	☐	Systematic Review	☐
Quantitative	☐	Biological samples/ Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

………

4. METHODOLOGY

(a) Sample size/ number of participants *(as applicable)*

At site……………. In India………………………….. Globally ……………………………………

Control group………………………………………Study group…………………………………………

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation

………

………

………

………………

[3]*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

(b) Is there an external laboratory/outsourcing involved for investigations?[4] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre ☐ No review ☐ research group Date of review:

Comments of scientific committee, if any (100 words) dd mm yy

.....

.....

.....

.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* .....

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/Friends ☐ visiting hospitals Telephone ☐

Others ☐ *(Specify)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally ill (stigmatized or rare diseases) ☐

Any other *(Specify)*: ☐ .....

iii. Provide justification for inclusion/exclusion .....

.....

.....

iv. Are there any additional safeguards to protect research participants?.....

.....

.....

[4] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU*

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

.....

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5] :

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy: .....

.....

.....

(b) What are the potential benefits from the study? For

	Yes	No	If yes,	Direct	Indirect
the participant	☐	☐		☐	☐
For the society/community For improvement in science	☐	☐		☐	☐
	☐	☐		☐	☐

Please describe how the benefits justify the risks .....

.....

.....

.....

(c) Are adverse events expected in the study[6] ? Yes ☐ No ☐ NA ☐

(d) Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify .....

.....

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes ☐ No ☐

.....

.....

[5] *For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*

[6] *The term adverse events in this regard encompass both serious and non-serious adverse events.*

(b) Version number and date of Participant Information Sheet (PIS):…… Version number and date of Informed Consent Form (ICF):……

(c) Type of consent planned for :

Signed consent ☐	Verbal/Oral consent ☐	Witnessed consent ☐	Audio-Video (AV) consent ☐
Consent from LAR (If so, specify from whom) ☐	For children<7 yrs parental/LAR consent ☐	Verbal assent from minor (7-12 yrs) alongwith parental consent ☐	Written assent from minor (13-18 yrs) along with parental consent ☐
Other ☐			

(specify) .....

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ *(Specify)* ……

Any tools to be used ……

(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐ *(Specify)*…… List the languages in which translations were done …… If translation has not been done, please justify ……

……

(f) Provide details of consent requirements for previously stored samples if used in the study[7]

……

……

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐
Alternatives to participation ☐	Confidentiality ☐	Commercialization/ Benefit sharing ☐
Right to withdraw ☐	Storage of samples ☐	Statement that study involves research ☐
Benefits ☐	Return of research results ☐	Use of photographs/ Identifying data ☐
Purpose and procedure ☐	Payment for participation ☐	Contact information of PI and Member Secretary of EC ☐
Others(Specify) ☐		

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8] ?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐

If yes, then who will provide the treatment? ……

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ N/A ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ N/A ☐

……

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes ☐ No ☐ N/A ☐

[7] *Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.8.*

[8] *Enclose undertaking from PI confirming the same*

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. *If Yes, specify* Yes ☐ No ☐ NA ☐

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) …….

……

……

……

……

(b) Who will be maintaining the data pertaining to the study? ……

(c) Where will the data be analyzed[9] and by whom? ……

(d) For how long will the data be stored? ……

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data inthefuture?……

……

……

……

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

……

……

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

……

……

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐ NA ☐

……

……

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐ NA ☐

……

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

……

[9] *For example, a data entry room, a protected computer etc.*

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guide- lines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, ,new clinical trial rules 2019 GCP-ASU guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-I): 1. .... 2. ....
☐	I/We declare/confirm that all necessary government approvals will beobtained asper requirements wherev- er applicable.

Name of PI: ..... Signature:

..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Guide: .....

Signature: ..... dd mm yy

Name of HOD: .....

Signature: ..... dd mm yy

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12	Copy of the detailed protocol[11]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
18	IRRB	☐	☐	☐		
19	Ayush Ministry	☐	☐	☐		
20	CCRAS	☐	☐	☐		
21	Tribal Board	☐	☐	☐		
22	Others (Specify)	☐	☐	☐		

OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
23	Ethical Committee fee Reciept	☐	☐	☐		
		☐	☐	☐		

**For multicentre research.*

MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Com- mittee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre

[11]*Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)*

(Annexure 1)

Application Form for Expedited Review

.....

EC Ref. No.* (For office use):

Title of study: .....

.....

..... Principal Investigator (Name, Designation and Affiliation): .....

1. Choose reasons why expedited review from EC is requested ?
   - i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   - ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   - iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   - iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   - v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   - vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   - vii. Formulticentre research where a designated EC hasapprovedthe proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited reviewdepending ontheimportance of local consent related issues involved specific to the centre. ☐
   - viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   - ix. Any other (please specify) .....

     .....
2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons[1] ? Yes ☐ No ☐

   If Yes give details: .....

   .....

   .....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[1]*For details, refer to application for initial review, Section-C, 5(b)* * *In case this is first submission, leave it blank*

(Annexure 2)

Application Form for Exemption from Review

.....

EC Ref. No. (For office use):

Title of study: .....

.....

..... Principal Investigator (Name, Designation and Affiliation): .....

1. Choose reasons why exemption from ethics review is requested[1]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[2] ☐
   - vii. Any other (please specify in 100 words): .....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[1] *Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[2] *Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

(Annexure 3)

Continuing Review / Annual report format

……………………..………………………………………………………………………………

EC Ref. No. (For office use):

Title of study: ……………………………......…………………………………………………………............................……………………………………………………..

………......................................……………………

………......................................……………………

Principal Investigator (Name, Designation and Affiliation): …………………………………..................……………………………………..

………......................................……………………

……….........…..................……………………

2. 1. Date of EC Approval: | 3. | 4. | 5. | 6. Validity of approval: | 7. | 8. | 9. | 10.

11.

12. Date of Start of study: | dd | mm | yy | 15. Proposed date of Completion: | dd | mm | 17. yy

13. Period of Continuing Report: 16. ---- to ------ 18.

14. Does the study involve recruitment of participants? | dd | mm | yy | | dd | mm | 19. yy

20. Yes ☐ No ☐

21.

22. If yes, Total number expected…………………… Number Screened: …………………… Number Enrolled: ………................ Number Completed:……...……………….........……………………… Number on followup:………………...…......……………………………….

23. Enrolment status – ongoing / completed/ stopped

24. Report of DSMB1 Yes ☐ No ☐ NA☐

25. Any other remark……...………..…….

26. ..……………......……………………………………………………………………..……………………………………………………………………… ………………………………......…..

27. Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA☐ If yes, total number withdrawn and reasons: ……………………………………………………………………………...…….

28. ……………………......………………………………………………………………..……………………………………………………………………… …………………....…………………….

29. ……………………......………………………………………………………………..……………………………………………………………………… …………………....…………………….

30.

31. Is the study likely to extend beyond the stated period ?2Yes ☐ No ☐

32. If yes, please provide reasons for the extension. ……………..…………………………………………………………………..……

33. ……………………......………………………………………………………………..……………………………………………………………………… …………………………………………..…..

34. ……………………………………………………………………………..……………………………………………………………….....…… ……………………………………………...………

35. Havetherebeenanyamendmentsintheresearch protocol/Informed Consent Document (ICD) duringthepast approval period?

36. If No, skip to item no. 6 Yes ☐ No ☐

37. If yes, date of approval for protocol and ICD : | dd | mm | yy |

38.

39. In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No☐ If yes, when / how: ……………………………………………………………………………..........………………...

40. ……………......………………………………………………………..………………………………………………………………………………… ………………………………………..……

41. ……………………………………………………………………………..………………………………………………………………….....………………

[1] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

[2] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

42. Is any new information available that changes the benefit - risk analysis of human participants involved in this study?
Yes □ No □

If yes, discuss in detail: ……

……

……

43. Have any ethical concerns occurred during this period? Yes □ No □

If yes, give details:……

……

44. (a) Have any adverse events been noted since the last review? Yes □ No □

Describe in brief: ……

……

……

(b) Have any SAE's occurred since last review? Yes □ No □

If yes, number of SAE's :…… Type of SAE's: ……

……

……

(c) Is the SAE related to the study? Yes □ No □

Have you reported the SAE to EC? If no, state reasons Yes□ No □

……

……

45. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations …… Have you reported the deviations to EC? If no, state reasons Yes□ No □

……

……

46. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes □ No □ NA □

47. Are there any publications or presentations during this period? If yes give details Yes□ No □

……

……

Any other comments:……

……

Signature of PI: …… dd mm yy

(Annexure 4)

Application/Notification form for Amendments

……

EC Ref. No. (For office use):

Title of study: ……

……

……

Principal Investigator (Name, Designation and Affiliation): ……

……

……

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [1]

3. Impact on benefit-risk analysis Yes □ No□

If yes, describe in brief: ……

……

4. Is any reconsent necessary? Yes □ No□

If yes, have necessary changes been made in the informed consent? Yes □ No□

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) □

Full review by EC (There is an increased alteration in the risk to participants) □

6. Version number of amended Protocol/Investigator's brochure/ICD: ……

Signature of PI: …… dd mm yy

[1] *Location implies page number in the ICD/protocol where the amendment is proposed.*

(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

……

EC Ref. No. (For office use):

Title of study: ……

……

……

Principal Investigator (Name, Designation and Affiliation): ……

……

……

1. Date of EC approval dd mm yy Date of start of study dd mm yy

2. Participant ID.....Date of occurrence dd mm yy

3. Total number of deviations /violations reported till date in the study: ……

4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐

SAE Sub Committee/EC ☐

5. Is the deviation related to (Tick the appropriate box) :

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others *(specify)*	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation: ……

……

……

……

7. Corrective action taken by PI/Co-I: ……

……

……

8. Impact on (if any): Study participant ☐ Quality of data ☐

9. Are any changes to the study/protocol required? Yes ☐ No☐ If yes, give details……

……

Signature of PI: …… dd mm yy

(Annexure 6)

Serious Adverse Event Reporting Format (Biomedical Health Research)

……

EC Ref. No. (For office use):

Title of study: ……

……

……

Principal Investigator (Name, Designation and Affiliation): ……..

……

……

1. Participant details :

Initials and ID	Age at the time of event	Gender	Weight .....(Kgs)
……	……	Male ☐ Female ☐	Height.....(cms)
……	……		

2. Suspected SAE diagnosis:……

3. Date of onset of SAE: dd mm yy

Date of reporting SAE: dd mm yy

Describe the event [1]:

……

……

……

……

……

……

4. Details of suspected intervention causing SAE [2]

……

……

……

……

……

5. Report type:Initial ☐ Follow-up ☐ Final☐

If Follow-up report, state date of Initial report dd mm yy

6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No☐

……

……

……

……

[1]*Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious* [2]*Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ? (Please list number of cases with details if available)

.....

.....

8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event ☐ Unexpected event ☐

B.

Hospitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

.....

In case of death, state probable cause of death

.....

C. No permanent/significant functional/cosmetic impairment ☐

Permanent/significant functional/cosmetic impairment ☐

Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).

.....

.....

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

.....

11. Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

.....

12. Provide any other relevant information that can facilitate assessment of the case such as medical history

.....

13. Provide details about PI's final assessment of SAE relatedness to research.

.....

.....

.....

Signature of PI: ..... dd mm yy

(Annexure 7)

Premature Termination/Suspension/ Discontinuation Report Format

…… ……

EC Ref. No. (For office use):

Title of study: ……

……

…… Principal

Investigator (Name, Designation and Affiliation): ……

1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation: ……

   ……

   ……

   ……

   Action taken post Termination/ Suspension/Discontinuation (if any): ……

   ……

   ……

5. Plans for post study follow up/withdrawal[1] (if any): ……

   ……

   ……

6. Details of study participants:

   Total participants to be recruited: …… Screened: …… Screen failures:……..

   Enrolled:…….. ConsentWithdrawn:…….. Reason (Give details): ……..

   ……

   ……

   Withdrawn by PI:…….. Reason (Give details): ……

   ……

[1] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

Active on treatment: ……..…… Completed treatment : ……..…… Participants on follow-up: ……..……

Participants lost to follow up: ……..…… Any other: ……..…….. Number of drop outs:……..

Reasons for each drop-out: ……..……..

……..

……..

7. Total number of SAEs reported till date in the study: ……..……..…… Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes □ No□

8. Have there been participant complaints or feedback about the study? Yes □ No□

If yes, provide details:……..……

……..……

9. Have there been any suggestions from the SAE Sub Committee? Yes □No□ If yes, have you implemented that suggestion? Yes □No□

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes □ No□ (e.g., making arrangements for medical care of research participants): If Yes, provide details

……..

……..

Summary of results (if any): ……..……..

……..

……..

……..

……..

……..

Signature of PI: …….. dd mm yy

(Annexure 8)

Application Form for Clinical Trials

.....

EC Ref. No. (For office use):

Title of study: .....

.....

..... Principal Investigator (Name, Designation and Affiliation): .....

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number: …… NABH accreditation number:..... EC registration number:.....

2. If regulatory trial, provide status of CDSCO permission letter
   Approved and letter attached ☐ Applied, under process ☐
   Not applied (State reason) ☐.....

3. Tick all categories that apply to your trial

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication	
Others (specify)	☐	or new route ofadministration	☐

.....

4. Trial design of the study

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Others *(specify)*	☐	Equivalence trial	☐

.....

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

.....

.....

III. Describe the method of allocation concealment (blinding / masking), if applicable.

.....

.....

5. List the primary / secondary outcomes of the trial.

.....

.....

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes☐No ☐

If yes, Name and Contact details: ……

……

……

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others *(specify)*	☐

……

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; if yes, provide regulatory approval details. Yes☐No ☐NA ☐

……

……

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details. Yes☐No ☐NA ☐

……

……

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

……

……

IV. Provide details of patent of the drug/s, device/s and biologics.

……

……

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, provide details (100words)……

……

……

……

……

9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[1]……

……

……

……

10. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention? If yes, provide details of arrangements made to address them. Yes□No □NA □

.....

.....

.....

11. Does the study use a placebo? If yes, justify the use of the placebo and risks entailed to participants. Yes□No □NA □

.....

.....

.....

12. Will current standard of care be provided to the control arm in the study? Yes□No □NA □

If no, please justify.

.....

.....

.....

13. Are there any plans to withdraw standard therapy during the study? If yes, please justify. Yes□No □NA □

.....

.....

.....

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes □ No □ NA □

.....

.....

.....

.....

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes□No□

.....

.....

.....

[1] *In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same*

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)
English ☐
Other*(Specify)* ☐ Local language ☐

(certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

..... List the languages in which translations were done .....
Justify if translation not done.....
.....

17. Involvement/consultation of statistician in the study design Yes☐No ☐NA ☐

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐No ☐

.....

.....

.....

I. Is the PI registered with National council for Indian systems of Medicine (NCISM) or the relevant State Ayush/ Medical Council registration?
Please provide details. Yes ☐ No ☐

.....

.....

II. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI: ..... d d mm yy

(Annexure 9)

Serious Adverse Event Reporting Format (Clinical trials)

.....

EC Ref. No. (For office use):

Title of study: .....

.....

..... Principal Investigator (Name, Designation and Affiliation): .....

1. Participant details :

Initials and Case No./ Subject ID	Age at the time of event	Gender	Weight..... (Kgs)
.....	.....	Male ☐ Female ☐	Height..... (cms)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

What was the assessment of relatedness to the trial in the initial report?

By PI – Related ☐ Unrelated ☐ By Sponsor – Related ☐ Unrelated ☐ By EC – Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

..

.....

..

4. Date of onset of SAE: dd mm yy Date of reporting: dd mm yy

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

.....

.....

....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

..

II. Indication(s) for which suspect study drug was prescribed or tested: ……..……..

.....……..

...

III. Route(s) of administration, daily dose and regimen, dosage form and strength :……

.....……..

..

IV. Therapy start date: dd mm yy Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes □ No □

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes □ No □

If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes□No □NA □

If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration: dd mm yy

.....……..

...

.....……..

... dd mm yy

II. Relevant test/laboratory data with dates:

.....……..

...

.....……..

...

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)…….……

.....……..

...

.....……..

...

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes□No□

.....……..

..

.....……..

..Seriousness of the SAE:

Death	□	Congenitial anomaly	□
Life threatening	□	Required intervention to prevent	
Hospitalization-initial or prolonged	□	permanent impairment / damage	□
Disability	□	Others *(specify)*	□

.....

12. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).

.....
..

.....
..

13. Outcome of SAE:

Fatal	□	Recovered	□
Continuing	□	Unknown	□
Recovering	□	Other *(specify)*	□

.....

14. Was the research participant continued on the trial? Yes □ No □ NA □

15. Provide details about PI's final assessment of SAE relatedness to trial.

.....
..

.....
..

16. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes □ No □
Provide details if communicated (including date)

17. Does this report require any alteration in trial protocol? Yes □ No □

18. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom)

.....

.....
.....

Signature of PI: ..... dd mm yy

(Annexure 10)

Study completion/Final report format

…… ……

EC Ref. No. (For office use):

Title of study: ……

……

……

Principal Investigator (Name, Designation and Affiliation): ……..

……

……

1. Date of EC approval: dd mm yy
2. Date of start of study: dd mm yy Date of study completion: dd mm yy
3. Provide details of:

a) Totalnumber ofstudy participants approved by the EC forrecruitment: ……

b) Total number of study participants recruited: ……

c) Total number of participants withdrawn from the study (if any): ……..

Provide the reasons for withdrawal of participants[1] :

……

……

……

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) ……

……

……

5. Describe the main ethical issues encountered in the study (if any) ……

……

……

……

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period Deviations: …….. Violation: …… Amendments: ……

7. Describe in brief plans for archival of records / record retention:……

……

……

[1] *Explanation for the withdrawal of participants whether by self or by the PI*

8. Is there a plan for post study follow-up? Yes ☐ No☐

If yes, describe in brief: ……

……

……

……

……

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No☐ If yes, describe in brief: ……

……

……

……

……

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No☐ If yes, describe in brief: ……

……

……

……

……

11. Describe results (summary) with Conclusion [2] : ……

……

……

……

……

12. Number of SAEs thatoccurredinthestudy: ……

13. Have all SAEs been intimated to the EC ? Yes ☐ No☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No☐ If yes, provide details……

……

……

……

Signature of PI: …… dd mm yy

[2] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

(Annexure 11)

Format for Curriculum Vitae for Investigators

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephone number: Email address:
Qualifications:
Professional registration *(Name of body, registration number and date of registration):*
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations):*
Projects undertaken in the last 5 years:

Relevant research training/experience in the area [1] :	
Relevant publications *(Give references to all relevant publications in the last five years):*	
Signature	Date:

References

1. Good Clinical Practices Guidelines for Clinical Trials in Ayurveda, Siddha, Unani medicine (ASU- GCP) pdf.
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