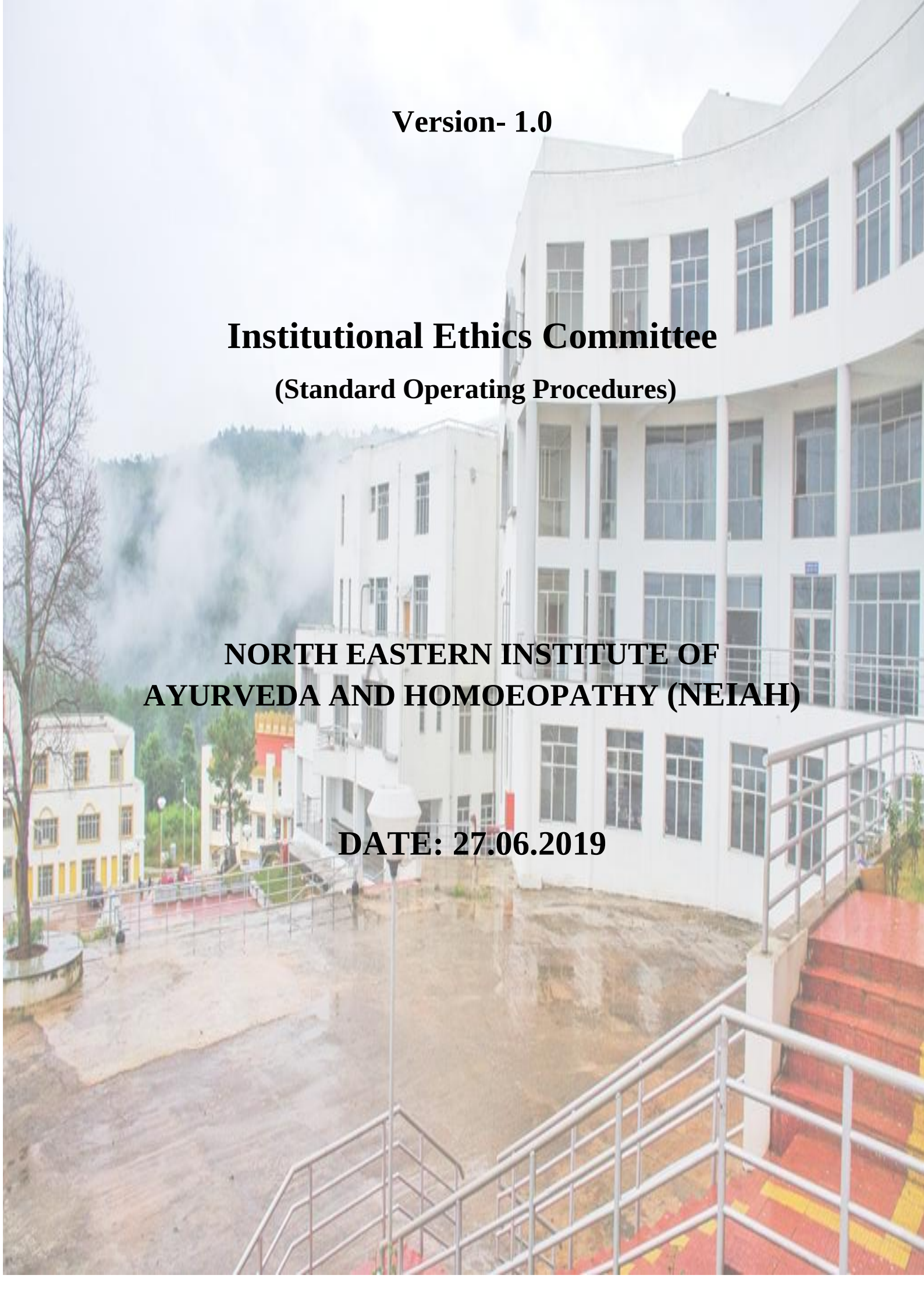

**Version- 1.0**

# Institutional Ethics Committee

## (Standard Operating Procedures)

## NORTH EASTERN INSTITUTE OF AYURVEDA AND HOMOEOPATHY (NEIAH)

## DATE: 27.06.2019

# CONTENT

# INTRODUCTION

North Eastern Institute of Ayurveda and Homoeopathy (NEIAH), Shillong is an autonomous institute established under the Ministry of AYUSH, Government of India established for medical education, research, and patient care especially in the North – East India. Among its objectives one of the mandates of NEIAH is to conduct research in various branches of medical sciences involving human population. The involvement of the human beings raises issues of ethics in research. Institutional Ethics Committee is required to be constituted in every such institute to ensure the ethical practices by the researchers.

NEIAH complies with Central Council for Research in Ayurvedic Sciences (CCRAS) guidelines and Good Clinical Practice (GCP) guidelines for Ayurveda Siddha and Unani (ASU) drugs.

In India, Ethical Committee for Research on Human Subjects presently functions according to the requirements laid down in Schedule Y of Drugs and Cosmetic Rule of 1945 and is guided by the (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use)-ICH GCP guidelines for Good Clinical Practice, and GCP-ASU guidelines in accordance to ASU drugs, ethical principles set forth in the classical text of authorative texts like *Charak Samhita* and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by Indian Council of Medical Research(ICMR).

## I. Short Title:

The following may be called as "Standard Operating Procedures (SOP) for the Institutional ethics committee (IEC) of North Eastern Institute of Ayurveda and Homoeopathy (NEIAH)"

## II. Adoption of SOP:

North Eastern Institute of Ayurveda and Homoeopathy, Shillong herein after referred to as "NEIAH" has adopted this written SOP to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at NEIAH.

### III. Objective:

The objective of this SOP is to maintain effective functioning of the IEC-NEIAH and to ensure quality and technical excellence and consistent ethical review of all the submitted biomedical, experimental and behavioural research proposals and ongoing approved research studies involving human participants in accordance with the CCRAS (series I, II and III) and CCRH guidelines.

### IV. Authority under which IEC-NEIAH is constituted:

The Director, NEIAH shall constitute the IEC in accordance with the SOP.

### V. Role and Responsibilities of IEC-NEIAH:

The IEC-NEIAH will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The basic responsibility of an IEC is to ensure a competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity. The IECs should specify in writing the authority under which the committee is established, membership requirements, the terms of reference, the conditions of appointment, the offices and the quorum requirements.

The mandate of the IEC shall be to review all research projects to be conducted at the Institute irrespective of the funding agency.

IEC-NEIAH will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee.

## VI. Composition of IEC:

a) IEC should be multidisciplinary and multi - sectorial in composition. Independence and competence are the two hallmarks of an IEC.
b) The number of persons in an Ethics Committee to be kept fairly small (5-7 members). It is generally accepted that a minimum of five persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a committee will make it difficult in reaching consensus opinion. 12 to 15 shall be the maximum recommended number.

The composition may be as follows:

a) Chairperson: A technical person with research background.
b) Member secretary.
c) Clinicians:1-2 Ayurvedic-Homoeopathy practitioners/ Clinicians from different Institutes.
d) Basic medical scientists: 1-2 basic medical scientists (one pharmacologist and one preferably from Dravyaguna / Rasa shastra / Bhaishajya Kalpana/Basic principles/Homoeopathy-Organon of Medicine/ Homoeopathic Pharmacy).
e) Legal expert: One Legal expert or retired Judge.
f) One social scientist / philosopher / ethicist / theologian / representative of Non-Governmental Voluntary Agency.
g) One common man representative from the community/society.

The Ethical Committee at any Institution can have as its members, individuals from other Institutions or Communities if required. There should be adequate representation of age, gender, community; etc. in the Committee to safeguard the interests and welfare of all sections of the Community/Society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required concerned subject experts could be invited to offer their views.

## VII. Membership requirements:

a) All members will serve for a period of 3 years on renewable basis. New members will be included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
b) During the term, Member in consultation with the Chairperson can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non availability.
c) A member can tender resignation of his office of membership from the IEC to the Member Secretary through the Chairperson after serving one month advance notice.
d) Chairperson/Member Secretary can replace the member of IEC as and when required.
e) Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Annexure-I)
f) Conflict of interest should be declared by members of the IEC-NEIAH prior to review meeting

**VIII. Quorum requirements:**

Minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member and one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals.

Quorum shall have 5 members with following representations:

a) Basic medical scientists (preferably one pharmacologist/ person from Dravyaguna).
b) Clinicians.
c) Legal expert.
d) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person.
e) Common man representative from the community/ society.

**IX. Conduct of IEC-NEIAH meetings:**

The Chairperson will conduct all meetings of the IEC-NEIAH. In the absence of the Chairperson Member Secretary will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

**X. Independent consultants:**

The IEC-NEIAH may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific community; patient groups or special interest groups E.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the IEC-NEIAH.

**XI. Submission of Application:**

The Investigator should submit an appropriate application to the IEC in a prescribed format along with the study protocol at least **three weeks** in advance. The application should include the following:

a) Clear research objectives and rationale for undertaking the investigation in the light of existing knowledge.
b) Recent curriculum vitae of the investigators indicating qualification and experience.
c) Participant recruitment procedures.
d) Inclusion and exclusion criteria for entry of participants in the study.
e) Precise description of methodology of the proposed research, including intended dosages and routes of administration of drugs, planned duration of treatment and details of invasive procedures if any.
f) A description of plans to withdraw or withhold standard therapies in the course of research.

g) The plans for statistical analysis of the study.
h) Procedure for seeking and obtaining informed consent with sample of participant information sheet and informed consent forms in English and vernacular languages.
i) Safety of proposed intervention and any drug to be tested, including results of relevant laboratory research.
j) For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage should be included.
k) Proposed compensation and reimbursement of incidental expenses.
l) Storage and maintenance of all data collected during the trial.
m) Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
n) A statement on probable ethical issues and steps taken to tackle the same.
o) All other relevant documents related to the study protocol including regulatory clearances.
p) Agreement to comply with national and international GCP protocols for clinical trials.
q) Details of Funding agency / Sponsors and fund allocation for the proposed work.

**XII. Documentation:**

All Research proposals (5 copies along with 1 CD) shall be submitted along with the information and documents as specified in Annexure-II (A) and (B).

**XIII. Review procedures:**

a. Meeting of the IEC-NEIAH will be held on periodic intervals, i.e. 1st Wednesday every four months, unless otherwise specified by the member secretary. 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 work load.
b. The proposals should be sent to the IEC-NEIAH at least 3 weeks in advance of schedule meeting.
c. The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved.
d. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.
e. Researchers will be invited to offer clarifications if need be. The Principal investigator (PI) / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal.
f. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
g. The decisions will be in minutes and Chairperson's approval taken in writing.

**XIV. Aspects considered during review of research proposal.**

a) Scientific design and conduct of the study.
b) Approval by appropriate scientific review committees.
c) Examination of predictable risks/harms
d) Examination of potential benefits.

e) Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
f) Patient information sheet, informed consent form in English and Vernacular languages.
g) Plans for data analysis and reporting.
h) Adherence to all regulatory requirements and applicable guidelines.
i) Competence of investigators, research and supporting staff.
j) Facilities and infrastructure of study sites.
k) Criteria for withdrawal of patients, suspending or premature termination of the study.

**XV. Decision Making Process**

The decision made by IEC-NEIAH must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The Member Secretary should communicate the decision in writing.

**Types of the decision by the IEC:**

The IEC-NEIAH can give one of the following decisions:

a) Approved - with or without suggestions or comments.
b) Revision with minor modifications/amendments - approval is given after examination by the Member Secretary or expedited review, as the case may be;
c) Revision with major modifications for resubmission - this will be placed before the full committee for reconsideration for approval; or
d) Not approved (or termination/revoking of permission if applicable) - clearly defined reasons must be given for not approving/terminating/revoking of permission.
e) A member must voluntarily withdraw from the IEC while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes.
f) If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed.
g) In situation where there will be Tie during voting, the decision will be taken by the Chairperson and in his/her absence by the Member Secretary.
h) A negative decision should always be supported by clearly defined reasons.
i) An IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit/risk ratio.
j) The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
k) In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.

The following circumstances require the matter to be brought to the attention of IEC:

a) Any amendment to the protocol from the originally approved protocol with proper justification.
b) Serious and unexpected adverse events and remedial steps taken to tackle them;
c) Any new information that may influence the conduct of the study.
d) If necessary, the Applicant/Investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the participant groups or interest groups can be invited during deliberations to offer their viewpoint.
e) Subject Experts may be invited to offer their views, but should not take part in the decision making process. However, her/his opinion must be recorded.
f) Meetings are to be Minutes which should be approved and signed by the Chairperson.

**XVI: Communicating the decision**

a) Decision of the meeting on the proposals will be communicated by the Member Secretary in writing to the PI / Research Scholar within 10 working days after the meeting at which the decision was taken in the specified format (Annexure-III).
b) A certificate of approval will be sent to the applicant within 2 weeks (Annexure-IV). All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project reapproved after one year if necessary.

**XVII. Following up procedures for approved proposals by PI / Sponsor:**

a) IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
b) Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
c) Final report should be submitted at the end of study.
d) Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
e) Change of investigators/sites must be informed to the office of IEC.
f) Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

**XVIII. Record keeping and archiving at the office of IEC-NEIAH:**

a) All documentation and communication of an IEC should be dated, filed and preserved according to written procedures.
b) Confidentiality should be maintained during access and retrieval procedures by designated persons.
c) All active and inactive (closed) files should be appropriately labelled and archived separately in designated areas.
d) Records can be maintained in hard copies as well as soft copies.

e) All records must be archived for a period of at least 3 years after the completion/termination of the study.
f) Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations.
g) Records may be archived for a longer period, if required by the sponsors/regulatory Bodies.
h) IEC should describe archival and retrieval mechanisms in SOPs.
i) IEC records should be accessible for inspection by authorized representatives of regulatory agencies.

**XIX. Updating IEC-NEIAH members:**

a) All relevant new guidelines should be brought to the attention of the members.
b) The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ (ies), so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

**XX. Terms of reference**

Terms of reference will be maintained in the office of IEC-NEIAH. This includes

a) Membership requirements.
b) Terms of appointment with reference to the duration of the term.
c) The policy for removal, replacement, resignation procedure.
d) Frequency of meetings.
e) Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts etc.

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

**XXI: ADMINISTRATION AND MANAGEMENT**

A full time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

## XXII: STANDARD OPERATING PROCEDURE TO BE FOLLOWED BY THE COMMITTEE IN GENERAL

### XXII.1 Name and Formation

This committee will be known as IEC-NEIAH. This name will remain unchanged.

### XXII.2 Objectives and Responsibilities

The primary objective of this committee will be:

a) To protect the right, safety and well being of the research subject and assist in welfare and benefit of the society.
b) To review the qualifications of all investigators participating in the proposed research study.
c) To keep all information submitted to them confidential especially, the proprietary information.
d) To review all research proposals submitted to the committee within the specified time limits
e) To maintain concise but clear documentation of its use on the research proposals.
f) To review the progress of each research project at appropriate and specified intervals and also review the summary of final report of the studies approved by them.

### XXII.3 Functions & Operations

#### XXII.3.1 Submission of the Research Proposals

a) All communications with the Committee will be in writing (physical or electronic)
b) Before receiving the review materials, it is advisable to obtain COI (Conflict of Interest) declaration and CA (Confidentiality Agreement) from the Member Secretary, Chairperson and Members.
c) In case of any amendment to the research proposal or any modification which is not suggested by the Committee and is not administrative, submission should be made to IEC.

## XXIII: SPECIAL CONSIDERATIONS / PROTECTION OF VULNERABLE POPULATION:

While all the above requirements are applicable to Ayurvedic/Homoeopathy/ Allopathy Medicine research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safeguards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC should be given in writing in unambiguous terms in such instances.

## XXIV: Informed Consent Process

The information should be given to the Participants and / or their legal representatives or guardians in a language and at a level of complexity that is understandable to the participant(s) in both written and oral form, whenever possible.

The Informed Consent Document (ICD) has two parts - (i) patient/participant information sheet (PIS) and (ii) the informed consent form (ICF). Information on known facts about the research, which has relevance to participation, is included in the PIS. This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research.

## XXV.1 Patient /Participant Information Sheet (PIS)

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language he or she is able to understand which should not only be scientifically accurate but should also be sensitive to their social and cultural context:

a) The aims and methods of the research.
b) The expected duration of the participant participation.
c) The benefits that might reasonably be expected as an outcome of research to the participant or to others.
d) Any alternative procedures or courses of treatment that might be as advantageous to the participant as the procedure or treatment to which she/he is being subjected.
e) Any foreseeable risk or discomfort to the participant resulting from participation in the study.
f) The extent to which confidentiality of records could be able to safeguard, confidentiality and the anticipated consequences of breach of confidentiality.
g) Free treatment for research related injury by the investigator / institution.
h) Compensation of participants for disability or death resulting from such injury.
i) Freedom of individual / family to participate and to withdraw from research any time without penalty or loss of benefits which the participant would otherwise be entitled to.
j) The identity of the research teams and contact persons with address and phone numbers.
k) Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same.
l) Risk of discovery of biologically sensitive information.
m) Publication, if any, including photographs and pedigree charts.
n) Information on standard of care (including modem medicine)

The quality of the consent of certain social groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

## XXV.2 Informed Consent form (Annexure-V)

### A) Informed Consent of Participant

Prior to the beginning of the study the investigators must obtain the Ethical Committee's approval for the written informed consent form and all information being provided to the participants and / or their legal representatives or guardians or an impartial witness in case participant /Legally Authorized Representative (LAR) is illiterate. None of the oral and written information concerning the Study, including the written informed consent form, should contain any language that causes the Participant(s) or their legal representatives or guardians to waive or to appear to waive their legal rights, or that releases or appears to release the Investigator, the Institution, the Sponsor or their representatives from their liabilities for any negligence.

This requirement is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research. Informed consent is a continuous process involving three main components - providing relevant information to potential participants, ensuring competence of the individual, ensuring the information is easily comprehended by the participants and assuring voluntariness of participation. Informed voluntary consent protects the individual's freedom of choice and respects the individual's autonomy.

**Requisites**

a) The participant must have the capacity to understand the proposed research, be able to make an informed decision on whether or not to be enrolled and convey her/his decision to the researcher in order to give consent.
b) The consent should be given voluntarily and not be obtained under duress or coercion of any sort or by offering any undue inducements.
c) In the case of an individual who is not capable of giving voluntary informed consent, the consent of LAR must be obtained.
d) It is necessary to maintain privacy and confidentiality of participants at all stages

### B) Informed Consent in Non-Therapeutic Study

In case of a Non-Therapeutic study the consent must always be given by the participant. Non-Therapeutic Studies may be conducted in participants with consent of a legal representative or guardian provided all of the following conditions are fulfilled:

a) The objective of the study cannot be met by means of a trial in Participants who can personally give the informed consent
b) The foreseeable risks to the Participant(s) are low.
c) Ethical Committee's written approval is expressly sought on the inclusion of such Participant(s).

## XXV.3 Documentation of Informed Consent process

a) Each prospective participant should sign the informed consent form after going through the informed consent process of receiving information, understanding it and voluntarily agreeing to participate in the research.
b) In case the participant is incompetent (medically or legally) to give consent, the LAR's consent must be documented.
c) The process of consent for an illiterate participant/LAR should be witnessed by an impartial literate witness who is not a relative of the participant and is in no way

connected to the conduct of research, such as other patients in the ward who are not in the study, staff from the social service department and counsellors. The witness should be a literate person who can read the participant information sheet and consent form and understand the language of the participant.

d) If the participant cannot sign then a thumb impression must be obtained.
e) The researcher who administers the consent must also sign and date the consent form.
f) In the case of institutionalized individuals, in addition to individual/LAR consent, permission for conducting the research should be obtained from the head of that institution.
g) In some types of research, the partner/spouse may be required to give additional consent.
h) In genetic research, other member of a family may become involved as secondary participants if their details are recorded as a part of the family history. If information about the secondary participants is identifiable then their informed consent will also be required.
i) Online consent may be obtained, for example, in research involving sensitive data such as unsafe sex, high risk behaviour, use of contraceptives (condoms, oral pills), or emergency contraceptive pills among unmarried females in India etc. Investigators must ensure that privacy of the participant and confidentiality of related data is maintained.

**XXV.4. Procedures after the consent process**

a) After consent is obtained, the participant should be given a copy of the PIS and signed ICF unless the participant is unwilling to take these documents. Such reluctance should be recorded.
b) The researcher has an obligation to convey details of how confidentiality will be maintained to the participant.
c) The original PIS and ICF should be archived as per the requirements given in the guidelines and regulations.

**XXVI Responsibilities of the Institution for conducting a research in alliance with industries/commercial companies**

Academic institutions conducting research in alliance with industries/commercial companies require a strong review to probe possible conflicts of interest between scientific responsibilities of investigators and business interests (e.g. ownership or part ownership of a company developing a new product. In cases where the review board/committee determines that a conflict of interest may damage the scientific integrity of a study or cause harm to research participants, the board should advise accordingly. Institutions need self-regulatory processes to monitor, prevent and resolve such conflicts of interest. Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research. Undue inducement through compensation for individual participants, families and populations should be prohibited. This prohibition however, does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care reimbursement, costs of travel and loss of wages and the possible use of a percentage of any royalties for humanitarian purposes.

**XXVII: Registration of clinical trial**

Clinical trials hold enormous potential for benefiting participants, improving therapeutic regimens and ensuring advancement in medical practice that is evidence based. Registration of trials will ensure transparency, accountability and accessibility of clinical trials. The Clinical Trials Registry- India (CTRI) hosted at the ICMR's National Institute of Medical Statistics (NIMS), is a free and online (www.ctri.nic.in) public record system for registration of clinical trials being conducted in India. Today, any Investigator who plans to conduct a trial involving human participants of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies as well as trials being conducted in the purview of the Ministry of AYUSH (ayush.gov.in) is expected to register the trial in the CTRI before enrolment of the first participant. Trial registration involves public declaration and identification of trial Investigators, Sponsors, Interventions, Participant population, Trial site, etc. before the enrolment of the first participant. Submission of Ethics approval and Ministry of AYUSH approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrolment are captured. After a trial is registered, investigators are expected to regularly update the trial status or other aspects as the case may be. After a trial is registered, all updates and changes will be recorded and available for public display. Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHO's search portal, the ICTRP as well as from the CTRI (www.ctri.nic.in).

**XXVIII: Address of the office of the Ethical committee:**

**North Eastern Institute of Ayurveda and Homoeopathy (NEIAH), Mawdiangdiang, Shillong-793018**

**Secretariat of IEC, NEIAH**

**Director Office, Administrative Block NEIAH, Shillong**

**Email: iec.neiah@gmail.com**

**Website: www.neiah.nic.in**

**Phone No: (0364)2520680/2538184**

**XXIX: Details of the Chairperson:**

**Prof. (Dr.) Vandana Raphael MD, DNB**
**Professor and Head**
**Department of Pathology**
**NEIGRIHMS, Shillong-793018**
**Email: raphaellyngdoh@gmail.com**
**Phone - 9436707442**

**XXX: Details of the members of the Ethics Committee:**

| Sl. No | Name | Designation/Contact details | Category/status |
|---|---|---|---|
| 1 | Prof. (Dr.) Vandana Raphael | Dean (Research) cum HOD, Department of Pathology, NEIGRIHMS,Shillong<br>Email:raphaellyngdoh@gmail.com<br>Phone - 9436707442 | Chairperson |
| 2 | Prof.Ramesh Sharma | Professor, Department of Biochemistry, school of life sciences, NEHU, Shillong<br>Email:sharamesh@gmail.com<br>Phone- 9436117141 | Vice- Chairperson |
| 3 | Prof(Dr).P.K. Goswami | Director , NEIAH<br>Email:pkgoswamibhu@gmail.com<br>Phone-9415385128 | Member Secretary |
| 4 | Dr Anuradha Roy | Dean(I/C), NEIAH,Shillong<br>Email:dranu369@yahoo.co.in<br>Phone: 9956630433 | Alternate Member Secretary |
| 5 | Prof. H. Lamin | Pro Vice-Chancellor, NEHU Shillong<br>Email: henrylamin30492@gmail.com | Social Scientist |
| 6 | Dr Himesh Barman | Associate Professor<br>HOD(I/C), Department of Pediatrics, NEIGRIHMS,Shillong<br>Email: himeshbarman@gmil.com<br>Phone : 8974054513 | Clinician |
| 7 | Dr.Bishnu Choudhury | Lecturer ,Department of Kayachikitsa, NEIAH,Shillong<br>Email: drbishnuchoudhury@gmail.com<br>Phone: 9401597062 | Clinician |
| 8 | Dr D.K. Brahma | Associate Professor<br>Department of Pharmacology, NEIGRIHMS,Shillong.<br>Email: dbdhriti168@gmail.com<br>Phone: 8794706170 | Basic Medical Scientist |
| 9 | Dr Rituparna Baroah | Associate Professor<br>Department of Physiology, NEIGRIHMS,Shillong<br>Email:drrituparnabarooah@gmail.com<br>Phone : 9436700733 | Basic Medical Scientist |
| 10 | Dr Binay Sen | Lecturer ,Department of Dravyaguna, NEIAH,Shillong<br>Email: senbinay@yahoo.co.in<br>Phone : 9936077418 | Basic Medical Scientist |
| 11 | Dr Himashree Bhattacharya | Assistant Professor<br>Department of Community Medicine, NEIGRIHMS,Shillong<br>Email:himashreebhattacharyya@gmail.com<br>Phone : 8638409689 | Basic Medical Scientist |
| 12 | Dr O P Patel | Lecturer ,Department of Homeopathic Pharmacy, NEIAH,Shillong<br>Email: omprakash21patel@gmail.com<br>Phone: 8085201456 | Basic Medical Scientist |

| | | | |
|---|---|---|---|
| 13 | Dr B P Chyne | Lecturer ,Department of Organon of Medicine, NEIAH,Shillong<br>Email: bakmenchyne2011@gmail.com<br>Phone: 9436775418 | Basic Medical Scientist |
| 14 | Shri Biplab Kr Das | Advocate, Shillong Bar Association, Shillong<br>Phone : 9774661460 | Lawyer |
| 15 | Mr Bijit Khongsit | President, Seva Bharati, Riblong, Shillong<br>Email :bijitkhongsit@gmail.com | Common man representative. |

**XXXI: Details of additional staff:**

**A) Dr Sikha Lekharu**
**Convenor, Research Unit**
**Email- shikhalekharu@gmail.com**
**Phone- 8811834122.**

**B) Mr Dhaneswar Choudhury**
**UDC**
**Phone- 7662896075**
**Email- choudhurydhaneswar@gmail.com**

**Annexure - I**

From,

_____

_____

_____

To,

The Director

NEIAH, Shillong-793018

Sub: Consent to be a member of Institutional Ethics Committee-(IEC-NEIAH) - Reg.

Ref: Your Letter No:_____ dated: _____

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC-NEIAH Shillong. 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 herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature _____

Name of the Member _____

Date: _____

Address: _____ _____

_____

Telephone No: _____

Email: _____

# APPOINTMENT ORDER

IEC-NEIAH

Dr/ Mr. / Mrs.: _____Date: _____

I am pleased to appoint you as _____ of the Institutional Ethics Committee (IEC) (Human research) at North Eastern Institute of Ayurveda and Homoeopathy (NEIAH) w.e.f._____ for a term of _____ year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.
3. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC-NEIAH.

You will be paid an amount as Honorarium for your services rendered & as per the guidelines given in Terms of Reference, IEC-NEIAH

We sincerely hope your association with IEC-NEIAH will be fruitful to the Institute & the Community we serve.

Chairperson
IEC-NEIAH
(Name/Seal)
Shillong-793018

Signature of Appointee

Name/Date

Member Secretary
IEC-NEIAH
(Name/Seal)
Shillong

# Institutional ethics committee- North Eastern Institute of Ayurveda and Homoeopathy (NEIAH)

## Initial Review Submission Form for Research Proposal

a. Title of the research proposal.
b. Name of the Principal Investigator (PI) with qualification and designation.
c. Name of the Co-Investigator(s) (Co-PI) with qualifications and designation if any.
d. Name of the Institute / Hospital / Field area where research will be conducted.
e. Forwarding letter from the Head of the Institution / Department /Guide.
f. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in the light of existing knowledge, inclusion and exclusion criteria. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, Plan to withdraw or withhold standard therapies in the course of research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.
g. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, Informed consent process, including patient information sheet and informed consent form in English and local language(s). Source of funding and financial requirements for the project.
h. Research proposals approval by scientific advisory committee.
i. Statement of conflicts of interest, if any.
j. Agreement to comply with the relevant, ASU- GCP protocols for clinical trials.
k. Curriculum vitae of all the investigators with relevant publications in last five years.
l. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
m. Any other information relevant to the study.
n. Signature of the Principal Investigator with date.

**Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal**

## FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH FOR CLEARANCE BY ETHICS COMMITTEE OF NEIAH:

Submit five (5) copies of the Research Project along with Covering letter and 'soft copy' on email **iec.neiah@gmail.com** along with a blank CD with the following information to the Member Secretary, Institution Ethics Committee of NEIAH, Tel No…….. The Principle Investigator must submit protocol forwarded through the Head of Department.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the Institution Ethics Committee with signatures of all the investigators. The submission must be accompanied with Participant Informed Consent Form (PICF) and Participant Information Sheet (PIS), both in English and Hindi/Concerned local Language, in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points, before it can be considered for placing before the Institution Ethics Committee. Also ensure that all the pages are numbered.

**Project Submission Time**: Submissions will be received on all working days. Proposals received till 15th of preceding month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held every four months as possible. The frequency will change depending upon the requirement.

While submitting replies raised by the Institution Ethics Committee, the candidates are advised to mention the Institution Ethics Committee reference number/s and also attach a copy of the comments of the Institution Ethic Committee.

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

## Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC), NEIAH

**(For attachment to each copy of the proposal)**

**Serial No of IEC Management Office:**

**Proposal Title:**

| | **Name, Designation, Department & Qualifications** | **Address Tel & Fax Nos. Email ID** | **No of projects already with Investigator** | **Signature** |
|---|---|---|---|---|
| PI | | | | |
| Co-PI / Collaborators<br><br>1. | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| **Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).** | | | | |

| |
|---|
| **1.Type of Study : Cross sectional □ case control □ cohort □ Clinical Trial □ Review□**<br>**Participating Centre: Single-centre □ Multi-centric □ Others (Specify)……..** |
| **2. Status of Review: New □ Revised □** |
| **3. Clinical Trials: Drug /Device/Herbal Remedies :**<br>**Does the study involve use of : Drug □ Devices □**<br><br>**Indian Systems of Medicine/ Homoeopathy Medicine □ Any other □ NA □** |
| **4. Brief description of the proposal –** Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words): |
| **5. Subject selection:**<br>**i. Number of Subjects :** |
| **ii. Duration of study :** |
| **iii. Will subjects from both sexes be recruited: Yes/No** |
| **iv. Inclusion / exclusion criteria given : Yes/No** |
| **v. Type of subjects: Volunteers □ Patients □** |
| **6. Privacy and confidentiality**<br>**i. Study involves - Blinding □**<br>**If YES Single □ Double □ Triple□** |
| **i. Is there a plan for reporting of adverse events?**<br>**ii. If Yes, reporting is done to : Sponsor □ Ethics Committee □** |
| **7. Do you have conflict of interest? (Financial/Non-financial)**<br>**If Yes, specify :** |
| **8. Whether any work on this project has started or not? □**<br><br>**(mark √ if yes, X if no) (Please enclose a separate certificate to this effect)** |

# Communication of Decision of the Institutional Ethics Committee (IEC)

**IEC No.**

| |
|---|
| Protocol title: |
| Principal Investigator: |
| Name & Address of Institution: |
| New review: □ Revised review: □ Expedited review:□ |
| Date of review (D/M/Y):<br>Date of previous review, if revised application: |
| Decision of the IEC: Recommended : □ Recommended with suggestions:□<br>Revision:□ Rejected: □ |
| Suggestions/ Reasons/ Remarks |
| Recommended for a period of : |

**Please note ***

- **Inform IEC immediately in case of any adverse events and serious adverse events.**
- **Inform IEC in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to IEC**
- **Members of IEC have right to monitor the trial with prior intimation.**

Signature of Member Secretary
IEC-NEIAH

**Annexure - IV**

# North Eastern Institute of Ayurveda and Homoeopathy-Institutional Ethics Committee

**No.** **IEC. ----------**

**Date: ----------**

## IEC APPROVAL NOTICE

**To**:

_____

**Date:**

**Re**: IEC Proposal No._____: [Title]

---

I am pleased to inform you that at the convened meeting of _____ the IEC voted to (**Recommend/Recommend with suggestions/Revision/Rejected**) the above referenced protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
2. Changes, amendments, and add-on to the protocol or the consent form must be submitted to the IEC for re-review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
3. Adverse events should be reported to the IEC. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review.
4. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file.
5. NEIAH IEC Office requires review of an approved study not less than once per 12-month period. Therefore, a continuing review application must be submitted to the IEC in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.

Sincerely,

Member Secretary, IEC Chairperson, IEC

**ANNEXURE: V**

## Sample Copy of Consent Form (English)

StudyTitle_____
Study Number_____
Subject's Full Name (with father's name) _____
Date of Birth/Age_____
Address of subject _____
_____
Qualification_____
Occupation: Student/self-employed/service/housewife/other (please tick as appropriate)
Annual income of subjects_____
Name and address of nominee(s) and his relation to subject_____
_____

1. I confirm that I have read and understood the information document dated _____for the above study and have had the opportunity to ask questions. OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the clinical trial/study, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study/ trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (blood) for future research. Yes ☐ No ☐
6. I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Signatory's Name_____ Date_____

Signature of the Investigator_____ Date_____

Study Investigator's Name _____

Signature of the Witness _____Date_____
Name of the Witness _____
Received a signed copy of Consent Form:
Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____ Date_____

**References:**


1. General Guidelines for Drug Development of Ayurvedic Formulations: Central Council of Research in Ayurvedic Sciences: Ministry of AYUSH: Government of India: New Delhi: series 1
2. General Guidelines for Safety/Toxicity evaluation of Ayurvedic Formulations: Central Council of Research in Ayurvedic Sciences: Ministry of AYUSH: Government of India: New Delhi: series 2
3. General Guidelines for Clinical Guidelines for Clinical Evaluation Of Ayurvedic Interventions: Central Council of Research in Ayurvedic Sciences: Ministry of AYUSH: Government of India: New Delhi: series 2
4. Institute Ethics Committee(Human Studies) Standard Operating Procedures: All India Institute of Medical Sciences, Bhubaneswar, Odisha-751019
5. NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS: ICMR 2017.