# North-Eastern Hill University
## Ethics Committee Mandate

This mandate follows ICMR guidelines (2017) for conducting and supporting any research involving human participants. All the departments of North-Eastern Hill University (NEHU) that conduct research involving human participants must follow these guidelines in both letter and spirit to protect the safety and well-being of all individuals. All proposals on research involving human participants and/or samples should be cleared by the NEHU Ethics Committee (IECHSP). The basic responsibility of the NEHU Institutional Ethics Committee of Human Samples and Participants (IECHSP) is to ensure the objective, competent review of all ethical aspects of the project proposals it receives. IECHSP should 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 an appropriate Scientific Review Committee. The following guidelines must be followed while conducting any research on humans.

**I. Principles of essentiality** whereby the research entailing the use of human participants is considered to be essential after a due consideration of all alternatives in the light of the existing knowledge in the proposed area of research.

**II. Principles of voluntariness, informed consent, and community agreement** whereby research participants are fully apprised of the research and the impact and risk of such research on the research participant and others; and whereby the research participants retain the right to abstain from further participation in the research irrespective of any legal or other obligation.

**III. Principles of non-exploitation** whereby, as a general rule, research participants are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research participants, they are kept fully apprised of all the dangers arising in and out of the research so that they can appreciate all the physical and psychological risks.

**IV. Principles of privacy and confidentiality** whereby the identity and records of the human participants of the research or experiment are, as far as possible, kept confidential; and that no details about the identity of said human participants, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons.

**V. Principles of precaution and risk minimisation** whereby due care and caution is taken at all stages of the research and experiment (from its inception as a research idea, its subsequent research design, the conduct of the research or experiment and its applicative use) to ensure

that the research participant and those affected by it including community are put to the minimum risk, suffer from no known irreversible adverse effects, and generally, benefit from and by the research or experiment.

**VI. Principles of professional competence** whereby the research is conducted at all times by competent and qualified persons who act with total integrity and impartiality and who have been made aware of, and are mindful of, preferably through training.

**VII. Principles of accountability and transparency** whereby the research or experiment will be conducted in a fair, honest, impartial, and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research, and any conflict of interest that may exist.

**VIII. Principles of public domain** whereby the research and any further research, experimentation, or evaluation in response to, and emanating from such research, is brought into the public domain so that its results are generally made known through scientific and other publications.

**IX. Principles of totality of responsibility** whereby the professional and moral responsibility, for the due observance of all the principles, guidelines, or prescriptions laid down generally or in respect of the research or experiment in question, devolves on all those directly or indirectly connected with the research or experiment, including the researchers.

**X. Principles of institutional arrangements** whereby there shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bona fide and transparent manner.

**REVIEW PROCEDURES**

The IECHSP should review every research proposal on human participants before the research is initiated. It should ensure that a scientific evaluation has been completed before ethical review is taken up. The Committee should evaluate potential risks to participants, provide appropriate justification, outline expected benefits, and assess the adequacy of documentation to ensure privacy, confidentiality, and justice. The IECHSP's member-secretary shall screen the proposals for completeness and, depending on the risk involved, categorize them into two types: exemption from review and full review (see below for explanations).

Minimal risk would be defined as one that may be anticipated to result in harm or discomfort no greater than that encountered in routine daily life activities of the general population or during routine physical or psychological examinations or tests. However, in some cases, such as surgery, chemotherapy, or radiation therapy, a significant risk would be inherent in the

treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions, since they would be undertaken as part of current everyday life.

An investigator cannot determine that their protocol falls within the exempt category without approval from the IECHSP. All proposals will be scrutinized to decide under which of the following two categories they will be considered:

**1. Exemption from review**

Proposals that present less than minimal risk fall under this category, as may be seen in the following situations:

i. Research on educational practices such as instructional strategies or the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Exceptions:**

i. When research on the use of educational tests, surveys, or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

ii. When interviews involve a direct approach or access to private papers.

**2. Expedited Review**

Proposals presenting no more than minimal risk to research participants may be subject to expedited review. The Member- Secretary and two designated members of the Committee or Subcommittee of the IEC may do an expedited review only if the protocols involve -

1. Proposals that are completely questionnaire and/or interview-based.
2. Minor deviations from originally approved research during the period of approval (usually of one year duration).
3. Continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

**3. Full Review**

All research presenting more than minimal risk, proposals/protocols that do not qualify for exempt review, and projects involving vulnerable populations and special groups shall be subject to full review by all members. While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a**. Collection of blood samples** by finger prick, heel prick, ear prick, or venipuncture:

i. from healthy adults and non-pregnant women who weigh within the normal range for their age;

ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected have been considered.

iii. from neonates, depending on the hemodynamic status, body weight of the baby, and other purposes;

iv. prospective collection of biological specimens for research purposes by non-invasive means.

b. **Collection of data through non-invasive procedures** like anthropometric body measurements;

i. physical sensors that are applied either to the surface of the body or at a

ii. weighing or testing sensory acuity;

iii. electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,

iv. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual.

c. **Collection of data from voice, video, digital, or image recordings** made for research purposes.

d. **Research on individual or group characteristics or behavior**, not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**I. INFORMED CONSENT PROCESS**

**1. Informed Consent of Participants:** For all research involving human participants, the investigator must obtain the informed consent of the prospective participant or, in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent protects the individual's freedom of choice and respect for autonomy, and is given voluntarily to participate in research or to decline participation. Adequate information about the research is given in simple, easily understandable, unambiguous language in a document known

as the **Informed Consent Form with Participant/ Patient Information Sheet**. The latter should have the following components as may be applicable:

1. Nature and purpose of the study, stating it as research

2. Duration of participation with the number of participants

3. Procedures to be followed

4. Investigations, if any, to be performed

5. Foreseeable risks and discomforts are adequately described, and whether the project involves more than minimal risk

6. Benefits to participant, community, or medical profession as may be applicable

7. Policy on compensation

8. Availability of medical treatment for such injuries or risk management

10. Steps taken for ensuring confidentiality

11. Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research or in case of injury

12. Voluntary participation

A copy of the participant/patient information sheet should be given to the participant for their records. The informed consent should be brief in content, highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits, and s/he could withdraw at any time without any consequences. Assurance is given that confidentiality will be maintained and that all investigations/interventions will be carried out only after consent is obtained.

**II. COMPENSATION FOR PARTICIPATION**

Participants may be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research.

**III. SELECTION OF SPECIAL GROUPS AS RESEARCH PARTICIPANTS**

**i.** ***Pregnant or nursing women***: Pregnant or nursing women should in no circumstances be participants in any research unless the research carries no more than minimal risk to the foetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy, and lactation. As a general rule, pregnant or nursing women should not be participants in any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant, or nursing would not be suitable participants.

**ii.** ***Children*****:** Before undertaking research in children, the investigator must ensure that -

a. Children will not be involved in research that could be carried out equally well with adults;

b. The purpose of the research is to obtain knowledge relevant to the health needs of children.

c. A parent or legal guardian of each child has given proxy consent.

**iii.** ***Vulnerable groups***: Efforts may be made to ensure that individuals or communities invited for research are selected in such a way that the burdens and benefits of the research are equally distributed.

a. Research on genetics should not lead to **racial inequalities**;

b. Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than they are;

c. The rights and welfare of **mentally challenged and mentally differently able persons** who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, the need for participation, the risks and benefits involved, and the privacy and confidentiality procedures. The entire consent process should be properly documented.

d. Adequate justification is required for the involvement of participants such as tribal/indigenous groups (particularly PVTGs), students, subordinates, employees, service personnel, etc., who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compelling reasons.

**IV. COMPENSATION FOR ACCIDENTAL INJURY**

Research participants who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability.