NORTH-EASTERN HILL UNIVERSITY
SHILLONG-793022

Application form for Clearance for PG/Ph.D./Project Proposal by Institutional Ethics Committee of Human Samples and Participants (IECHSP)

IECHSP#_____ Date of Submission:_____
(To be completed by the IECHSP Office)

Proposal Title:

1. Name of the Principal Investigator:
    a. Designation:
    b. Department of:
    c. Address:
    d. Telephone No.:
    e. E-mail ID:
2. Name and address of the Co-Principal Investigator/ Collaborator (please attach an additional page for more than 4 collaborators):

	Collaborator 1	Collaborator 2	Collaborator 3	Collaborator 4
Name				
Designation				
Department of				
Address				
Telephone No.				
E-mail ID				
Signature				

3. Name of Department/Center where the study will be conducted:

4. (a) Approval of the Department/Center obtained? YES ☐ NO ☐
   (b) Funding Source:

5. **Type of Study**: Epidemiological ☐ Basic Sciences ☐ Clinical ☐
Behavioral ☐ Sociological ☐

6. If Clinical, Single-center ☐ Multicentric ☐ Not applicable ☐
Drug use ☐ Vaccine use ☐
Invasive ☐ Non-invasive ☐ Other ☐

Specify:

7. **Subject selection**:

a) Number of Subjects:

b) Duration of study: Years Months

c) Will subjects from both sexes be recruited YES ☐ NO ☐

d) Inclusion/Exclusion criteria given YES ☐ NO ☐

e) Type of subjects Volunteers ☐ Patients ☐

8. **Vulnerable subjects** (Tick the appropriate boxes)

NONE ☐ Pregnant women ☐ Children ☐
Elderly ☐ Fetus ☐ Illiterate ☐
Differently abled ☐ Terminally ill ☐ Seriously ill ☐
Mental Health-related issue ☐
Economically & socially backward ☐ Any other ☐

9. **Privacy and confidentiality**

i. Study involves –

Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymized/ delinked ☐

ii. Confidential handling of data by staff YES ☐ NO ☐

10. Detail protocol and synopsis of the proposed proposal human samples/participants:

Attach (ANNEXURE: A**)**

11. Ethical issues in the study and plans to address the issues:

12. **Consent:** *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form: (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study-related injury	☐	eg. genetic basis for drug development	

*If written consent is not obtained, give reasons:

ii. Who will obtain consent?

PI ☐ Co-PI ☐ Nurse/Counselor ☐

Researcher ☐ Any other ☐

Specify:

13. A brief statement explaining the process of obtaining informed consent:
Attach (ANNEXURE: B**)**

14. Will any advertising be done for the recruitment of Subjects?
(posters, flyers, brochures, websites – if so, kindly attach a copy)

15. **Risks & Benefits:**

i. Is the risk reasonable compared to the anticipated benefits to subjects/community/ country?

ii. Is there physical / social / psychological risk / discomfort?

If Yes,
- Minimal or no risk ☐
- More than minimum risk ☐
- High risk ☐

16. Is there compensation for participation?

If Yes, Monetary ☐ In-kind ☐
Specify amount and type:

17. Is there compensation for injury?

If Yes, by Sponsor ☐ by Investigator ☐
by insurance ☐ by any other ☐
company ☐

18. Copies of Proforma / Case report forms /Questionnaires/Follow-up, etc.

Attach (ANNEXURE: C**)**

19. Detailed information on the project, including Introduction, Objectives, Methods, Inclusion and/or Exclusion criteria, and Time plan

Attach (ANNEXURE: D**)**

20. For any drug /device trial, all relevant publications/pre-clinical data and clinical trial data from other centers within the country and/or other countries, if available:

21. Curriculum vitae of the Investigator(s) with relevant publications:

Attach (ANNEXURE: E**)**

22. Regulatory clearances (other than IEC of NEHU) required, if any:

23. An agreement to report only Serious Adverse Events (SAE) to IECHSP:

24. Statement of conflict of interest, if any:

25. A statement satisfying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants, such as the human subjects involved as participants in the trial (as defined in the guidelines of the various national agencies), the researches themselves, and such other persons who may be directly or indirectly at risk in the conduct of the research.

26. Plans for publication of results, positive or negative, while maintaining the privacy and confidentiality of the study participants:

27. Any other information relevant to the study:

Declaration

I, **Dr/Ms/Mr_____,** Department of_____, and I/we agree to comply with the guidelines/decision of IEC, NEHU, Shillong as well as the ethical guidelines of relevant national agencies for conducting on human sample/participants.

Signature of Principal Investigator (PI)
Date:
Place:

Signature of Head of Department
Date:
Place:

Signature of Students/ Co-Principal Investigator (CO-PI)
Date:
Place: