(Annexure 1)

Application Form for Expedited Review

Institute Ethics Committee

National Institute of Technology Meghalaya

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

ute

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

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

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

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

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

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

1. Choose reasons why expedited review from EC is requested12 ?
	1. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and 

left-over clinical samples.

* 1. Involves clinical documentation materials that are non-identifiable (data, documents, records). 
	2. Modification or amendment to approved protocol (administrative changes/correction of typographical 

errors and change in researcher(s)).

* 1. Revised proposal previously approved through expedited review, full review or continuing review of 

approved proposal.

* 1. Minor deviation from originally approved research causing no risk or minimal risk. 
	2. 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.

* 1. For multicentre research where a designated EC has approved the proposal, a participating EC may  review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre.
	2. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). 

ix. Any other (please specify) …………………………………………………………………………………………………...........................................…

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

1. Is waiver of consent being requested? Yes  No 
2. Does the research involve vulnerable persons13 ? Yes  No 

If Yes give details: …………………………………………………………………………………………………...............................................................………

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

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

Signature of PI: ……………………………………………………………………………................…………........................…………

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

Comments of EC Secretariat: ……………………………………………………………………………............................................................……………

Signature of Member Secretary: ……………………………………………………..............…………….........................……

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

*12 Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*

*13For details, refer to application for initial review, Section-C, 5(b)*

*\* In case this is first submission, leave it blank*

*Version 2.0*