(Annexure 4)

Application/Notification form for Amendments

Institute Ethics Committee

National Institute of Technology Meghalaya

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



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

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

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1. Date of EC approval:

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

1. Details of amendment(s)

Date of start of study

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S.No | Existing Provision | Proposed Amendment | Reason | Location in the protocol/ICD 18 |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Impact on benefit-risk analysis Yes  No

If yes, describe in brief: ………………………………………………………………………………………………………………………………………....…....………

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

1. Is any reconsent necessary? Yes  No

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

1. 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) 

1. Version number of amended Protocol/Investigator’s brochure/ICD: ………………………………………………

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

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

*18Location implies page number in the ICD/protocol where the amendment is proposed*

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

 *Version 2.0*