(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

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 Date of start of study

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

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

1. Participant ID: Date of occurrence

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

3. Total number of deviations /violations reported till date in the study: ………………………....................................…………….........

1. Deviation/Violation identified by: Principal Investigator/study team  Sponsor/Monitor 

SAE Sub Committee/EC 

1. Is the deviation related to (Tick the appropriate box) :

|  |  |  |
| --- | --- | --- |
| Consenting |  Source documentation |  |
| Enrollment |  Staff |  |
| Laboratory assessment |  Participant non-compliance |  |
| Investigational ProductSafety Reporting |  Others *(specify)* |  |

6. Provide details of Deviation/Violation: ………………………………………………………………………………….................................………………

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7. Corrective action taken by PI/Co-I: …………………….………………………………………………………………………….................................……..

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1. Impact on (if any): Study participant  Quality of data 
2. Are any changes to the study/protocol required? Yes  No If yes, give details…………………………………………….....................................…………………………….……………………………………………………….

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

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

*Version 2.0*