



(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

Institute Ethics Committee

Indian Institute of Technology, Delhi

EC Ref. No. (For office use):

Title of study:

.....

..... Principal

Investigator (Name, Designation and Affiliation):

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1. Date of EC approval

dd mm yy

Date of start of study

dd mm yy

2. Participant ID:..... Date of occurrence

dd mm yy

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

4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐

SAE Sub Committee/EC ☐

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

Consenting ☐

Source documentation ☐

Enrollment ☐

Staff ☐

Laboratory assessment ☐

Participant non-compliance ☐

Investigational Product ☐

Others (specify) ☐

Safety Reporting ☐

6. Provide details of Deviation/Violation:

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

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8. Impact on (if any): Study participant ☐ Quality of data ☐

9. Are any changes to the study/protocol required?

Yes ☐ No ☐

If yes, give details.....

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Signature of PI:

dd mm yy