

Protocol Violation/Deviation Reporting Form (Reporting by case)

Logo of the
Institute

.....
(Name of the Institution)

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

2. Participant ID: Date of occurrence

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: