



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

IEC No. of the Project:

Annexure 1 AX 01/SOP 10/V 7.1 Protocol Violation/Deviation Reporting Form (Reporting by case)

Date:

Study Title:

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Principal Investigator (Name, Designation & 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. Deviations/Violations identified by:

Principal Investigator/Study team Sponsor/Monitor SAE Sub Committee/EC

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

| | | | |
|-------------------------|--------------------------|----------------------------|--------------------------|
| Consenting | <input type="checkbox"/> | Source Documentation | <input type="checkbox"/> |
| Enrollment | <input type="checkbox"/> | Staff | <input type="checkbox"/> |
| Laboratory assessment | <input type="checkbox"/> | Participant non-compliance | <input type="checkbox"/> |
| Investigational Product | <input type="checkbox"/> | Others (Specify) | <input type="checkbox"/> |
| Safety Reporting | <input type="checkbox"/> | | |

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 Participants Quality of data

9. Are any changes to the study/Protocol required? Yes No

If Yes, give details

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Signature of Principal Investigator (PI) with Date: