



# 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 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: .....