Annexure 1
AX 01 / SOP 10/V6
Deviation / Non-compliance / Violation Record

(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. .....

Title of study: .....

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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-PI: .....

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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

Version 1.0