

**Annexure 1**  
**AX 01 / SOP 10/V6.1**  
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: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

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 <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 ( <i>specify</i> ) <input type="checkbox"/>
Safety Reporting <input type="checkbox"/>	

6. Provide details of Deviation/Violation: .....

.....

.....

.....

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

.....

.....

.....

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.....

.....

.....

Signature of PI: .....