

**Annexure 01/SOP/11/V2.1**

**Protocol Violation / Deviation Reporting Form (Reporting by case**)

SMVMCH-EC Ref. No. (for office use) :

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

1. 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

1. Provide details of Deviation/Violation:
2. Corrective action taken by PI/Co-PI:
3. Impact on (if any): Study participant Quality of data
4. Are any changes to the study/protocol required? Yes No

If yes, give details

Signature of PI with date