



INSTITUTIONAL ETHICS COMMITTEE

(Annexure 5)

PANJAB UNIVERSITY (PUIEC), CHANDIGARH-160014

Protocol Violation/Deviation Reporting Form (Reporting by case)

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

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:

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

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: