

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi

Version 2; 31 May, 2022

Annexure 13. Protocol Violations/Deviations Reporting

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: [Click here to enter a date.](#) Date of start of study: [Click here to enter a date.](#)
2. Date of EC approval: [Click here to enter a date.](#) Date of start of study: [Click here to enter a date.](#)
2. Participant ID: Date of occurrence: [Click here to enter a date.](#)
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:

[Click here to enter a date.](#)