



(Annexure 5)
Protocol Violation/ Deviation Reporting form (Reporting by case)
अखिल भारतीय आयुर्वेद संस्थान
All India Institute of Ayurveda (AIIA)

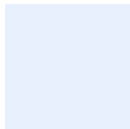
EC Ref. No. (for office use):

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. 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.](#)