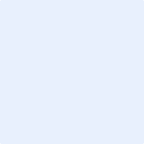
|  |  |
| --- | --- |
| **Logo of the Institute** | **(Annexure 5)**  **Protocol Violation/ Deviation Reporting form (Reporting by case)**    ***(Name of the Institution)***  **EC Ref. No*.(****for office use):* |

|  |
| --- |
| 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 |  | 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-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.