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

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| Title of study:       Principal Investigator (Name, Designation and Affiliation)      |

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| 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.