



Maratha Vidya Prasarak Samaj's  
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**(Annexure 5)**  
**Protocol Violation/ Deviation Reporting form (Reporting by case)**  
EC Ref. No. (for office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation)

- Date of EC approval: \_\_\_\_\_ Date of start of study: \_\_\_\_\_
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              | <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:

Date: