

***Annexure 20***  
***Deviation / Violation Record***

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| IEC Protocol no.:                                                                                                                                                                                                                                                         |  |
| Study Title:                                                                                                                                                                                                                                                              |  |
| Principal Investigator:                                                                                                                                                                                                                                                   |  |
| Department:                                                                                                                                                                                                                                                               |  |
| <div style="display: flex; justify-content: space-between; align-items: flex-start;"><div style="width: 45%;"><input type="checkbox"/> Deviation from protocol</div><div style="width: 5%;"></div><div style="width: 50%;"><input type="checkbox"/> Violation</div></div> |  |
| Description of deviation (s)/violation(s)<br><br>Corrective Actions Taken by the Principal Investigator:                                                                                                                                                                  |  |
| Reported by (Name of Principal Investigator/ Study Team Member):<br><br>_____<br><br>Signature with date:                                                                                                                                                                 |  |

**Provisional Decision by the Reviewer (Member Secretary and/or Chairperson and/or IEC Member/s)**

- Noted
- Request the PI not to perform such deviations/ non compliances/ violations in future
- Specific recommendations stated below to be followed
- Suspend the study till the IEC recommendations are implemented Suspend the study till information available
- Terminate approval of the current study  
Reasons for termination
- Refuse subsequent applications from PI
- To discuss at the full Board meeting
- Any other \_\_\_\_\_

**Reviewed by**

**Name/s:**

**Signature/s with date:**

**Discussion of the protocol deviation/violation at the**

☐ Emergency meeting on \_\_\_\_\_

☐ Next Scheduled full board meeting on \_\_\_\_\_

Final decision at  
the full board  
meeting held on

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**Signature with date IEC  
Member Secretary**