# *Deviation/ Violation Record*

IHEC Protocol no:

Study Title:

Principal Investigator:

Department:

Deviation from protocol:

Protocol violation:

Description of deviation (s)/violation(s):

Corrective Actions Taken by the Principal Investigator:

Reported by (Name of Principal Investigator/ Study Team Member):

Signature with date: _____

**Provisional Decision by Reviewer (Member Secretary/ Additional Member Secretary and/or Chairperson and/or IHEC Member/s)**

- Noted
- Request the PI not to perform such deviations/ non compliances/ violations in future
- Specific recommendations stated below to be followed

**Specific recommendations stated below to be followed**

- Suspend the study till the IHEC 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

**Signature with date**

**IHEC Member Secretary**