



KMCT
MEDICAL COLLEGE

APPLICATION FORM NO: 6
INSTITUTIONAL ETHICS COMMITTEE,
KMCT MEDICAL COLLEGE

Manassery (P.O), Mukkam, Kozhikode, 673602
Protocol Violation/ Deviation Reporting form
(Reporting by case)

IEC Ref. No. _____ (for office use)

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of IEC 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	☐	Source documentation	☐
Enrolment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others (<i>specify</i>)	☐
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:

Date: