



APPLICATION FORM NO: 5
INSTITUTIONAL ETHICS COMMITTEE,
KMCT MEDICAL COLLEGE

Manassery (P.O), Mukkam, Kozhikode, 673602
APPLICATION/ NOTIFICATION FORM FOR
AMENDMENTS

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. Details of amendment(s)

SL. No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD

3. Impact on benefit-risk analysis

Yes ☐ No ☐

If yes, describe in brief.

4. Is any re-consent necessary?

Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent?

Yes ☐ No ☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants)

☐

Full review by EC (There is an increased alteration in the risk to participants)

☐

6. Version number of amended Protocol/Investigator's brochure/ICD:

Signature of PI:

Date: