



(Annexure 4)
Application/ Notification form for Amendments

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. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD ¹⁸

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:

¹⁸Location implies page number in the ICD/protocol where the amendment is proposed.