



(Annexure 5)

Application/Notification form for Amendments

Apollo Institute of Medical Sciences & Research, Chittoor Andhra Pradesh.517127

EC Ref. No. (For office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval:

dd mm yy

Date of start of study

dd mm yy

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 reconsent 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:

dd mm yy

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