

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):

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dd mm yy

1. Date of EC approval: dd mm yy 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 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.