



# INSTITUTIONAL ETHICS COMMITTEE

PANJAB UNIVERSITY (PUIEC), CHANDIGARH-160014

## Application/Notification form for Amendments

(Annexure 4)

EC Ref. No. (For office use):

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

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 <sup>18</sup>

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: .....

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