



# INSTITUTIONAL ETHICS COMMITTEE

(Annexure 12)

PANJAB UNIVERSITY (PUIEC), CHANDIGARH-160014

## Study completion/Final report format

EC Ref. No. (For office use):

Title of study: .....

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

1. Date of EC approval: [dd] [mm] [yy]

2. Date of start of study: [dd] [mm] [yy]      Date of study completion: [dd] [mm] [yy]

3. Provide details of:

- a) Total number of study participants approved by the EC for recruitment: .....
- b) Total number of study participants recruited: .....
- c) Total number of participants withdrawn from the study (if any): .....

Provide the reasons for withdrawal of participants<sup>23</sup> : .....

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) .....

5. Describe the main ethical issues encountered in the study (if any) .....

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period  
Deviations: ..... Violation: ..... Amendments: .....

7. Describe in brief plans for archival of records / record retention:.....

<sup>23</sup> Explanation for the withdrawal of participants whether by self or by the PI

8. Is there a plan for post study follow-up?

Yes  No

If yes, describe in brief: .....  
.....  
.....  
.....

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

Yes  No

If yes, describe in brief: .....  
.....  
.....  
.....

10. Is there a plan for post study benefit sharing with the study participants?

Yes  No

If yes, describe in brief: .....  
.....  
.....  
.....

11. Describe results (summary) with Conclusion <sup>24</sup> :

.....  
.....  
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.....

12. Number of SAEs that occurred in the study:

.....

13. Have all SAEs been intimated to the EC ?

Yes  No

14. Is medical management or compensation for SAE provided to the participants?

Yes  No

If yes, provide details.....  
.....  
.....  
.....

Signature of PI: .....

dd mm yy

<sup>24</sup> For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.