

INDUSTRIAL RESEARCH AND CONSULTANCY CENTRE

Office of the Dean R&D, IIT Bombay

Format for submission of Study Completion Report

(To be filled by principal Investigator)

- 1) IEC Project No.
- 2) Project Title:
- 3) Principal Investigator:
- 4) Department:
- 5) Date of IEC Approval
- 6) Duration of the study:
- 7) Version of proposal and ICF used in the study:
- 8) Summary of participants in study:
 - a. No. of participants approved by IEC
 - b. No. of recruited participants
 - c. No. of completed participants
 - d. No. of participants who refused to consent
- 9) Has there been amendment to the study submitted to IEC? Yes/ No

If yes, select the area of amendment and give detailed account on a separate sheet,

- A) Number of participants Yes/ No
- B) Study design Yes/ No
- C) Consent form Yes/No
- D) Change in equipment Yes/ No
- E) Any other change Yes/ No

- 10) Please mention date of amendment approval by IEC.

11) Has there been external monitoring of the study? Yes/ No

If yes, please submit the report

12) Have there been developments during the study leading to conflict of interest?

Yes/ No, If yes, please describe.

13) Has any participant expressed concern about confidentiality? Or complained otherwise?

Yes/ No, If yes, give details as a separate sheet

14) Has any SAEs been reported? Yes/ No

If yes, has it been intimated to IEC and what are the actions taken?

15) Have any participants withdrawn from study? IF yes, Mention the reason and action taken

16) Please submit a brief write-up on the study outcome with details of numbers of participants, enrolled, completed etc.

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1) IEC Meeting date (If reviewed in the meeting):

2) Final Decision:

Signature of Chairperson/Member Secretary with date