Title: Review of Study Completion reports

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report submitted for studies approved by the Institutional Ethics Committee (EC).

2. Scope

This SOP applies to the review of the Study Completion Report which is a written report of every completed study submitted by the Principal Investigator (PI).

3. Responsibility

It is the responsibility of the Secretariat/ EC Chairman/ Member Secretary/ Member/s to review the study report and act on it.

4. Detailed instructions

4.1. Receipt of Study Completion Report

- The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format – *AX 01/SOP 13/V3* from the PI. The study completion report is expected from the investigator within 1 month of completion of the study at the site.
- The Secretariat will follow instructions as in SOP 06/V3 (Management of Protocol Submission) for receiving and checking the report package.
- It is the responsibility of the EC Secretariat to review the report for completeness.
- The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form- *AX 01/SOP 13/V3* and forward it to the Member Secretary within 7 working days of receipt.
- The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full board meeting.

- If there is a need felt (e.g. a deviation/ violation is noted), the Member Secretary will handle it as per SOP 11/V3
- The Secretariat shall include the Study Completion Report Form in the agenda for EC members as per SOP 08/V3 for discussion at the full board meeting.

4.2. During the Board meeting

- The Member Secretary will present the report and members can discuss as needed.
- Following the discussion, the Chairman may take one of the following decision:
  a) noted / approved
  b) request for additional information / clarification
- The Secretariat will note the decision in the meeting minutes
- The Member Secretary will draft a letter to the PI conveying decision on the study completion report.
- The study shall be considered as closed if the decision by EC is "Noted" or "Approved".
- The Secretariat will accept and file the Report and get the Study Completion Report Form *AX 01/SOP 13/V3* signed by the Chairman.
- The final report will be placed in the master file and kept in the archival area.
- The Administrative Officer will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

5. Reference to other applicable SOPs:

- **SOP 06/V3**: *Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review*
- **SOP 08/V3:** *Agenda Preparation, Meeting Procedures and Recording of Minutes*
- **SOP 11/V3:** *Review of Protocol Deviations / Violations*

6. Annexures

Annexure 1 - Study Completion / Final report format (*Annexure 01/SOP/13/V3)*

Annexure 01/SOP-13/V3

Study Completion / Final report format

SMVMCH-EC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval :
2. Date of start of study: Date of study completion:
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 (*Explanation for the withdrawal of participants whether by self or by the PI)* :
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:
8. Is there a plan for post study follow-up? Yes☐ No☐

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?
   If yes, describe in brief: Yes ☐ No ☐

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 (*For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready)* :

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 with date:

_____

7. Flow chart

No.	Activity	Responsibility
1	Receipt of the study completion report	EC Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	EC Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to the Member Secretary	EC Secretariat
4	Review of the Study completion report for completeness and informing members at full-board meeting	Member-Secretary/
5	Inclusion of the report/ review at full-board meeting	EC Secretariat
6	Discussion and decision at the full board meeting	Member Secretary/ Chairman
7	Noting the decision in the minutes of the Meeting	EC Secretariat
8	Conveying decision to the Principal Investigator	EC Secretariat
9	Archiving all the study-related documents along with the Study completion report	Administrative Officer

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/.

2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

	Name	Designation	Signature
Prepared	Dr. Nishanthi. A	Member	
	Dr. Ganesh. R	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	3/11/22