Title: Management of Premature Termination / Suspension / Discontinuation of the study

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (EC) manages premature termination/suspension/discontinuation of a research study.

Protocols may be terminated/suspended/discontinued at the recommendation of the EC, Data Safety Monitoring Board (DSMB), Principal Investigator (PI), Sponsor, Regulator or other authorized bodies wherein participant enrolment and follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study previously approved by the EC that has been recommended for termination/suspension/discontinuation before its scheduled completion.

3. Responsibility

It is the responsibility of the EC to manage the termination of any study (recommended for termination by Data Safety and Monitoring Board, Principal Investigator, Sponsor or other authorized bodies or by the EC) that the EC has previously approved. The Secretariat is responsible for management of the premature termination/ suspension/discontinuation process.

4. Detailed instructions

4.1. Receipt of Recommendation for Study Termination.

- The Secretariat will receive the study protocol termination/suspension/discontinuation report submitted by the PI and verify the contents of the report for completeness (*AX 01/ SOP 14/V3*) and/or other documents (letter from PI / sponsor).

4.2. Review by the EC

- The Secretariat will inform the Chairman and Member Secretary regarding the recommendation for premature termination/ suspension/ discontinuation of study protocol and the termination/ suspension/ discontinuation report within 3 working days of receipt of the report.

- The Member Secretary/ Chairman shall review the report and either call for an emergency meeting or discuss the report at the regular full board meeting.
- The Secretariat will arrange for an Emergency meeting/ keep matter for discussion at full board meeting as per SOP 07A/V3.
- The Member Secretary in the meeting will inform members of the premature termination/ suspension/ discontinuation of the project and the reasons for the same.
- If the Premature termination/ suspension/discontinuation Report is unclear or more information is required from the PI, the Chairman shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- The Chairman shall sign and date the study termination/ suspension/ discontinuation report in acknowledgement.
- If the EC has revoked approval/suspended the study, regulatory authorities and Head of the institution must be informed within 14 working days of the full board meeting

4.3 Notifying the Principal Investigator

- The Secretariat will prepare a notification letter and send to the PI within 14 working days after the meeting acknowledging the approval of termination/ letter seeking clarifications/information regarding the premature termination.
- In case a letter is sent seeking clarifications/information regarding the premature termination/ suspension/ discontinuation, the PI shall send a written response within 60 days of receiving the letter.
- If the PI does not comply, the matter will be put to the full board meeting for discussion.
- The investigator may appeal or respond to the convened EC in writing.

4.4 Store the Protocol Documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file to archive.
- The protocol documents will be stored for a period of 5 years from the date of project Termination.

4.5 **Recommendation for Termination/ Suspension/ Discontinuation** ***4.1 By PI / Sponsor***

- An investigator/ Sponsor may put on hold a previously approved research when in the judgment of the investigator/ Sponsor this is appropriate to protect the rights or welfare of participants or when new safety information has appeared in the literature, or evolved from this or similar research.

4.6 By EC

EC members/Chairman can prematurely terminate/ suspend/ discontinue the study in he following situations:

- protocol non-compliance/violation following which EC decides in full board meeting to terminate/ suspend/ discontinue the study.
  - SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
  - When research is not conducted in accordance with EC policies, is not in compliance with the local regulations or that has been associated with unexpected serious harm to participants.
  - Zero accrual for 1-2 years or long-term, low accrual.

Suspended protocols remain open and require continuing review.

The EC may revoke approval and recommend to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

5. References to other applicable SOPs

SOP 07A/V3 - *Initial Full-Board Review of Research Study Protocols*

6. Annexure

Annexure 1 - Premature Termination/Suspension/ Discontinuation Report Format

(*Annexure 01/SOP/14/V3)*

Annexure 01/SOP/14/V3

Premature Termination/Suspension/ Discontinuation Report Format

SMVMCH-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. Date of last progress report submitted to EC:
3. Date of termination/ suspension/discontinuation:
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation:

   Action taken post Termination/ Suspension/Discontinuation (if any):

5. Plans for post study follow up/withdrawal *(Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study)* (if any):

6. Details of study participants:

   Total participants to be recruited:_____ Screened:_____ Screen failure:

   Enrolled:_____ Consent Withdrawn:_____

   Reason (Give details):

   Withdrawn by PI:_____

   Reason(Give details):
   Active on treatment:_____Completed treatment: :_____ Participants on follow-up:_____ Participants lost to follow up: _____

   Any other:_____Number of drop outs:_____

7. Total number of SAEs reported till date in the study:

   Have any unexpected adverse events or outcomes observed in the study been reported to the EC?

   Yes☐ No☐

8. Have there been participant complaints or feedback about the study? Yes☐ No ☐
   If yes, provide details:

9. Have there been any suggestions from the SAE Sub Committee? Yes☐ No☐
   If yes, have you implemented that suggestion? Yes☐ No ☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?

    Yes☐ No ☐

    (e.g., making arrangements for medical care of research participants): If Yes, provide details

    Summary of results (if any):

    Signature of PI with date:

7. Flowchart

No.	Activity	Responsibility
1	Receive recommendation for study termination/ suspension / discontinuation	EC Secretariat
2	Review and Discuss the Termination/ suspension/ discontinuation report	EC members, Member Secretary and Chairman
3	Notify the Principal Investigator	EC Secretariat
4	Store the Protocol Documents	EC Secretariat

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

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