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1. Purpose

This SOP describes how an IRB proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the IRB, Data Safety Monitoring Board (DSMB), Director General, sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study approved by Ethiopian Public Health Institute IRB that is being recommended for termination before its scheduled completion.

3. Responsibility

It is the responsibility of the IRB to terminate any study that the IRB has previously approved when the safety or benefit of the study participants is doubtful or at risk and data integrity is compromised momentously. The Secretariat is responsible for management of the termination process.

4. Flow chart

No.	Activity	Responsibility
1	Recommendation for study termination ↓	IRB/DSMB/Sponsor/Director General/Other authorized body
2	Receive recommendation for study termination ↓	Principal Investigator and IRB Secretariat
3	Review and Discuss the Termination Package ↓	IRB Secretariat, Chairperson and IRB members
4	Notify the Principal Investigator ↓	IRB Secretariat
5	Store the Protocol Documents ↓	IRB Secretariat
6	Inactivate the Protocol Document	IRB Secretariat

5. Detailed instructions

5.1. Recommendation for study termination

- Written recommendation for study termination may be presented by DSMB, IRB members, Scientific Director, Sponsor or other authorized bodies for study protocol termination.

5.2. Receive recommendation for study termination

- The IRB secretariat or the principal investigator receives recommendation for study protocol termination
- Inform the principal investigator or the study office to prepare and submit a protocol termination package
- Receive the study protocol termination package prepared and submitted by the principal investigator or the study office
- Verify the contents of the package for inclusion of:
    - Request for Termination Memorandum (EPHI-IRB AF 01-019/02.0, see Annex1.)
    - The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.
    - Original Continuing Review Application Form (EPHI-IRB AF 01-015/02.0), see Annex 1)
    - Termination is indicated under “Action Request”.
    - Completeness of the information, including accrual data since the time of the last continuing review
    - Presence of the required signatures (Principal Investigator).
- Initial and date the package upon receipt

5.3. Review and discuss the termination Package

- Notify the chairperson regarding the recommendation for study protocol termination
- Send a copy of the termination package to the Chairperson within one working day upon receipt
    - The chairperson reviews the results, reasons and accrual data

- The chairperson calls for an emergency meeting to discuss about the recommendation
- Types of decision after discussion on termination
  - ☐ Approved
  - ☐ Request information
  - ☐ Recommend further action
- If the termination approved:
  - The chairperson signs and dates the Continuing Review Application Form in acknowledgment and approval of the termination.
  - The chairperson returns the form back to the Secretariat within five working days of receipt of the package.
  - The secretariat reviews, signs, and dates the Continuing Review Application Form indicating that the termination process is complete.

5.4. Notify the Principal Investigator

- Make a copy of the completed Continuing Review Application Form
- Send the copy to the principal investigator for their records within seven working days

5.5. Store the protocol documents

- Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file
- Send the file to archive
- Store the protocol documents indefinitely for issues under or suspected of being under court case, if not, for five years

5.6. Inactivate the protocol documents

- Place the study protocol into the ***inactive*** protocol folder in the computer records under the following directory:
  p:\studyfiles\inactive protocols

6. Glossary

Study Termination	Permanent cessation of all research activities.
Suspension	Temporary cessation of some or all research activities.

7. References

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.
3. Associated SOP: SOP# EPHI-IRB 015/02.0.

8. Annex

Annex 1: Study Termination Memorandum
(EPHI-IRB AF 01-019/02.0)

PROTOCOL NUMBER:		EPHI-IRB-☐☐☐-☐☐☐☐	
PROTOCOL TITLE:			
PRINCIPAL INVESTIGATOR:			
PHONE :		E-MAIL:	
INSTITUTE:			
SPONSOR:			
IRB APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS:		NO. ENROLLED:	
SUMMARY OF RESULTS			
ACCRUAL DATA:			
PI SIGNATURE:		DATE:	