Title: Management of Study Termination

SOP Code: SOP/18/V1.2

Effective date: 03/10/2017

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1. Purpose

This procedure describes how an IEC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Scientific Director, 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 NIRRH Ethics Committee for Clinical Studies that is being recommended for termination before its scheduled completion..

3. Responsibility

It is the responsibility of the IEC Chairperson to terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process.

4. Flow chart

No.	**Activity**	**Responsibility**
1	Receive recommendation for study termination ↓	IEC Secretariat
2	Review and Discuss the Termination Package ↓	IEC Secretariat and Chairperson
3	Notify the Principal Investigator ↓	IEC Secretariat
4	Store the Protocol Documents ↓	IEC Secretariat
5	Inactivate the Protocol Document	IEC Secretariat

5. Detailed instructions

5.1 Receive recommendation for study termination.

- Receive recommendation and comments from IEC members, Scientific Director, Sponsor or other authorized bodies for study protocol termination.
- Inform the principal investigator to prepare and submit a protocol termination package.
- Receive the study protocol termination package prepared and submitted by the principal investigator
- Verify the contents of the package for inclusion of:
- Request for Termination Memorandum (AF/EC/05/06/V1.5, see ANNEX 5 of the SOP 06/V1.5.)

- The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data as listed below

- Original Continuing Review Application Form (AF/EC/03/06/V1.3), see ANNEX 3 of SOP/06/V1.3.
- 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.

5.2 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.
- The Chairperson signs and dates the Protocol Termination Application Form in acknowledgment and approval of the termination.
- The Chairperson returns the form back to the Secretariat within 5 working days of receipt of the package.
- The Secretariat reviews, signs, and dates the Protocol Termination Application Form indicating that the termination process is complete.

5.3 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 7 working days.

5.4 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 for five years.

5.5 Inactivate the protocol documents.

- Place the study protocol into the ***inactive*** protocol folder.

6. Glossary Nil

7. References

7.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

7.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

ANNEX 1 **AF/EC/1/18/V1.2**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.1	24th September 2014	Change in the Annexure nos.
Dr. Ragini Kulkarni	Version 1.2	7th November 2017	Pg. 3, 5.1, Details changed for reference of Annexure of Termination report