Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Management of Study Termination/ Suspension/ Discontinuation

SOP Code: 17/V1.5 Dated: 8th November 2024 Page Nos: 207 to 210

17.1. 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 participant enrollment and participant follow-up are discontinued before the scheduled end of the study.

Discretion of committee to terminate if not initiated in 3 years since approval

17.2. Scope

This SOP applies to any study approved by ICMR-NIRRCH Ethics Committee for Human Studies that is being recommended for termination before its scheduled completion.

17.3. Responsibility

It is the responsibility of the IEC Chairperson to terminate any study that the IEC has previously approved when the safety or benefit to the study participants is doubtful or at risk.

If participants are exposed to interventions at the time of premature termination, committee discusses how they will be taken care of and informed about the termination along with options for continued care. Principal investigator should assure the post intervention care to the participants.

The Secretariat is responsible for the management of the termination process.

17.4. Flow chart

Sr. No.	**Activity**	**Responsibility**
1	Receive a 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

17.5. Detailed instructions

17.5.1 Receive a recommendation for study termination.

a. Receive recommendations and comments from IEC members, Scientific Director, Sponsor or other authorized bodies for study protocol termination.
b. Inform the principal investigator to prepare and submit a protocol termination package.
c. Receive the study protocol termination package prepared and submitted by the principal investigator

d. Verify the contents of the package for inclusion of:

1. Request for Termination Memorandum (**AF/11/06/V2.2**, see ANNEX 11 of the SOP 06/V2.2)

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

i Original Continuing Review Application Form (**AF/8/06/V2.2**), see ANNEX 8 of SOP/06/V2.2.

ii Termination is indicated under "Action Request".

iii Completeness of the information, including accrual data since the time of the last continuing review.

iv Required signatures of Principal Investigator/ Co-investigator(S) with date on the package upon receipt.

17.5.2 Review and discuss the Termination Package.

i Notify the Chairperson regarding the recommendation for study protocol termination.

ii Send a copy of the termination package to the Chairperson within one working day upon receipt.

iii The Chairperson reviews the results, reasons and accrual data.

iv The Chairperson calls for an emergency meeting to discuss about the recommendation.

v The Chairperson signs and dates the Protocol Termination Application Form in acknowledgment and approval of the termination.

vi The Chairperson returns the form back to the Secretariat within 5 working days of receipt of the package.

vii The Secretariat reviews, signs, and dates the Protocol Termination Application Form indicating that the termination process is complete.

17.5.3 Notify the Principal Investigator.

i Make a copy of the completed Continuing Review Application Form

ii Send the copy to the principal investigator for their records within 7 working days.

17.5.4 Store the protocol documents.

i Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file.

ii Send the file to archive.

iii Store the protocol documents for five years.

17.5.5 Inactivate the protocol documents.

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

17.6 ANNEX

ANNEX 1 AF/01/17/V1.4 Document History

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Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	3rd May 2013	Final approved copy
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
Dr. Beena Joshi	Version 1.3	1st May 2019	SOP no. changed from 18 to 17 Suspension/ Termination added in the title.
Dr. Vikrant Bhor	Version 1.4	8th November 2024	All bullets are numbered. ● 17.3 2nd paragraph added