Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Preparation of SOPs for ICMR-NIRRCH Ethics Committee for Human Studies and Guidelines for Ethics Committees

SOP Code: 01/V1.6 Dated: 08th November 2024 Page Nos: 5 to 15

1.1. PURPOSE

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing, and amending SOPs within the ethics committee (ICMR-NIRRCH Ethics Committee for Human Studies).

The SOPs will provide clear, unambiguous instructions so that the related activities in the ethics committee are conducted in accordance with the WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, National Guideline for Ethics Committees, and ICH (International Conferences on Harmonization) Good Clinical Practice (GCP) and Ethical Guidelines for Biomedical Research by ICMR (2017)

1.2. SCOPE

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ethics committees (ICMR-NIRRCH Ethics Committee for Human Studies).

1.3. RESPONSIBILITY

The Secretariat of the ethics committee is responsible for appointing the SOP Team to formulate the SOPs, following the same procedures, format, and coding system when drafting or editing any SOP of the institute.

Secretariat of IEC:

Comprises of Member Secretary, Joint Member Secretary & Secretariat Staff

1. Coordinates activities of writing, reviewing, distributing and amending SOPs
2. Maintains on file all current SOPs and the list of SOPs
3. Maintains an up-to-date distribution list for each SOP distributed
4. Distribute the SOPs with a receipt to all users
5. Ensures all ethics committee members and involved administrative staff have access to the SOPs
6. Ensures the ethics committee members and involved staff are working according to the current version of SOPs

SOP team:

Comprises of Member Secretary, internal and external members

1. Proposes required SOPs and makes a Draft list
2. Select the format and coding system
3. Draft the SOP and get it reviewed by members
4. Assesses the request(s) for SOP revision in consultation with the secretariat and Chairperson.

Chairperson of the ethics committee:

1. Review and approve the SOPs
2. Signs and dates the approved SOPs

Head of the Institution

- **Once the SOP is finalized the Institution Director will accept it. The SOP effective date will be after the date of this signature.**

1.4. FLOW CHART

Sr. No.	**Activity**	**Responsibility**
1	Appoint the SOP Team	Chairperson
2	Write and List all relevant SOPs	SOP Team
3	Design a format and layout	SOP Team
4	Approves a new/revised SOP	Chairperson
5	Implement, distribute, and file all SOPs	Secretariat
6	Review and request for a revision of existing SOPs	SOP Team / IEC members/ administrative staff/Chairperson
7	Manage and archive superseded SOPs	Administrative Staff

1.5. Detailed instructions

1.5.1 Appoint the SOP Team

The *Chairperson* appoints the appropriate individuals who thoroughly understand the ethical review process to form the SOP writing team.

1.5.2. List all relevant SOPs

Make a list of all the SOPs, which are relevant for the functioning of the Ethics committee.

1.5.3. Format and layout

a. Each SOP should be given a self-explanatory number and an easily understood title. Each SOP will be prepared according to the template for Standard Operating Procedures in **AF/02/01/V1.6**.

b. Each page of the SOP will bear a header with the effective date in the left-hand corner. The SOP chapter number will be mentioned in the center while right-hand corner of the header will mention the name of the IEC.

c. The left-hand corner of the footer will bear the title of the SOP and page number in the right hand corner.

d. A unique code number with the format ICMR-NIRRCH XX/VV.w will be assigned to each SOP by the Bioethics cell.

   i. XX- will be a two-digit number assigned specifically to a SOP.

   ii. VV- refers to the version of the SOP

   iii. w- will be a number identifying the version

   iv. For e.g. ICMR-NIRRCH SOP 01/V1.6 is SOP number 01 with VV.w=version no. 1.6 which means six minor revisions to the SOP 01. The details of the time-to-time revisions should be explained in the Document history annexure.

e. Each SOP will be prepared according to the standard template.

1.5.4. Design the format

a. Each Annexure (AF) will be given a unique code number with the format AF/n/xx/Vy. e.g. AF/01/01/V1.6 indicates AF is Annexure; n is Annexure no. 1, xx is SOP no. 01 & V1.6 is Version 1.6 of SOP 01 of IEC-ICMR-NIRRCH.

b. Each Appendix (AP) will be given an unique code number with the format APn/Vy e.g.AP1/V 1.6 indicates AP is Appendix, n is Appendix no 1 , V 1.6 is version no. 1.6.

c. The first page of the SOP document will be signed and dated by the SOP team members, the IEC members who have reviewed the SOPs, the IEC Chairperson who has approved and the Director, ICMR-NIRRCH who has accepted the SOPs. The SOP will be implemented within 2 weeks after acceptance by the Director.

1.5.5 Write the SOP and approve new SOP

a. A draft will be written by the member secretary/ member of the SOP team
b. The draft SOP will be discussed with the other members of the SOP sub-committee members.
c. The final version will be passed to the Chairperson for review and approval.
d. Finally, the SOP will be endorsed by the Director of the Institute
e. If a new Director is appointed, the SOP's latest version needs to be endorsed afresh by her/him.

1.5.6. Implement, distribute and file all SOPs

a. The approved SOPs will be implemented from the effective date.
b. The approved SOPs will be distributed to the EC members and the relevant staff by the Secretariat. When a revised version is distributed, the old version will be retrieved from the members and destroyed. However, one copy of the old version will be retained at the Secretariat.
c. One complete original set of current SOPs will be filed centrally in the SOP Master file, by the secretariat of the ethics committee and kept in the Ethics Committees office.

1.5.7. Review and request for a revision of an existing SOP

a. Any member of the ethics committee, secretariat or administrative staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure; or if there is any change in the regulatory guidelines should use the form (Annex-5) to make a request.
b. If the SOP Team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the person who requested the decision.
c. Revision of the SOPs will be reviewed and approved in the same manner as new SOPs and will be done as per the change in regulations (section 5.4).

1.5.8. Manage and archive **OBSOLETE** *SOPs*

a. Previous versions of SOPs followed at ICMR – NIRRCH Ethics Committee for Human Studies are mentioned below.

Sr. No	Version of SOP	Effective Date
1.	Version 1	May 3, 2013
2.	Version 2	September 24, 2014
3.	Version 3	September 1, 2016
4.	Version 4	November 7, 2017
5.	Version 5	May 1, 2019
6.	Version 6	January 4, 2021
7.	Version 6.1	February 26, 2021

These versions should be marked as OBSOLETE and archived in the historical file in the EC Secretariat for records

1.6. ANNEX

ANNEX 1	List of SOPs	AF/01/01/V1.6
ANNEX 2	Template for SOP	AF/02/01/V1.6
ANNEX 3	Document History template	AF/03/01/V1.6
ANNEX 4	Log of SOP Recipients	AF/04/01/V1.6
ANNEX 5	Request for Revision of an SOP	AF/05/01/V1.6
ANNEX 6	Document History	AF/06/01/V1.6

LIST OF STANDARD OPERATING PROCEDURES VERSION-7

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ANNEX 2 **AF/02/01/V1.6**

Standard Operating Procedures Template

Effective date:	SOP 01/V1.6	IEC, ICMR-NIRRCH

Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Preparation of SOPs for ICMR-NIRRCH Ethics Committee for Human Studies and Guidelines for Ethics Committees

SOP Code: *SOP/xx/vv.w* **Effective Date:** *dd/mm/yyyy* **Pages:**

1. Purpose
2. Scope
3. Responsibility
4. Flow chart
5. Detailed instructions

6 Annex (Annex no. with title and code)

Main Text:

1. **Purpose** – summarizes and explains the objectives of the procedure.
2. **Scope** – states the range of activities that the SOP applies to.
3. **Responsibility** – refers to person(s) assigned to perform the activities involved in the SOP
4. **Flow chart** – simplifies the procedures in step-by-step sequence and states the responsible person(s) or position for each activity
5. **Detailed instructions** – describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.
6. **Annexure** – documents that explain further or clarify complex descriptions. “Description-by-example” is always recommended to avoid difficult texts which may be hard to understand.

ANNEX 3 **AF/03/01/V1.6**

Document History template

(The final version is the version after the approval by the Chairperson which is V1.0)

Author –	**Version**	**Date**	**Describe the main change**
Name	V1.0	dd-mm-yy	final version
Name	V1.1	dd-mm-yy	Minor changes
Name	V2.0	dd-mm-yy	Major changes
Name	V2.0 dd-mm-yy	No change	(routine review)

ANNEX 4 **AF/04/01/V1.6**

Log of SOP Recipients

No.	**Name of Recipients**	**SOP Code**	**No. of Copies**	**Signature**	**Date**
1	Chairperson	SOP/01/V1.0 SOP/02/V1.0 SOP/03/V1.0			
2	Dr. XXXX	SOP/01/V1.0 SOP/02/V1.0 SOP/03/V1.0			

ANNEX 5 **AF/05/01/V1.6**

Request for Revision of an SOP

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP/01/V1.0

Title:

Details of problems or deficiency in the SOP:

Change in regulation:

Identified by: Date (D/M/Y):

Discussed with:

SOP revision required: ☐ Yes ☐ No

If yes, to be carried out by whom?

If no, why not?

Date SOP re-finalized:

Date SOP approved:

Date SOP becomes effective:

ANNEX 6 **AF/06/01/V1.6**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	24th September 2014	Change in the serial no. of SOPs and addition of SOP on Audio – Visual consent Reference of KEM SOPs added
Dr. Ragini Kulkarni	Version 1.2	7th November 2017	Pg.5 Added in 5.6, point 1 'or there is any change in the regulatory guidelines' Added in point 3 - and will be done as per the change in regulations Pg.12, Added in Annexure 5 Change in regulation: Pg.7 Change in Page Nos. of SOPs
Dr. Beena Joshi	Version 1.3	1st May 2019	SOP nos. & Page nos. revised as per SOP 5 KEM recent SOP version updated in Reference no. 7.4
Dr. Beena Joshi	Version 1.4	4th January 2021	SOP modified from V5 to V6 SOP 01 modified as V1.4 SOP 15 modified as V1.4 SOP 27 is added.
Dr. Beena Joshi	Version 1.5	26th February 2021	Inclusion of study title in informed consent for future storage form (Annex 1.7 of SOP 6)
Dr. Vikrant Bhor	Version 1.6	8th November 2024	All bullets are numbered. Modifications done in following points: 1.3 Responsibility 1.5.3. Format and layout 1.5.4. Design the format 1.5.5 Write the SOP and approve new SOP 1.5.8. Manage and archive OBSOLETE SOPs