Title: Writing, Reviewing, Distributing and Amending SOPs

SOP Code: SOP/01/V1.3

Effective date: 07/11/2017

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1. PURPOSE

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the ethics committee (NIRRH Ethics Committee for Clinical 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 Harmonisation) Good Clinical Practice (GCP) and Ethical Guidelines for Biomedical Research by ICMR (2006).

2. SCOPE

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ethics committees (NIRRH Ethics Committee for Clinical Studies).

3. RESPONSIBILITY

It is the responsibility of the secretariat of ethics committee to appoint the SOP Team to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the institute.

Secretariat of IEC:

- Co-ordinates activities of writing, reviewing, distributing and amending SOPs
- Maintains on file all current SOPs and the list of SOP
- Maintains an up-to-date distribution list for each SOP distributed
- Distributes the SOPs with a receipt to all users
- Ensures all ethics committee members and involved administrative staff have access to the SOPs
- Ensures the ethics committee members and involved staff are working according to current version of SOPs

SOP team:

- Proposes required SOPs and makes a Draft list
- Selects the format and coding system
- Drafts the SOP in consultation with the SOP team formed and involved supportive staff
- Assesses the request(s) for SOP revision in consultation with the secretariat and Chairperson.

Chairperson of the ethics committee:

- Reviews and approves the SOPs
- Signs and dates the approved SOPs

4. FLOW CHART

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7	Manage and archive superseded SOPs	Administrative staff

5. Detailed instructions

5.1 Appoint the SOP Team

The *Chairperson* appoint the appropriate individuals who have a thorough understanding of ethical review process to form the SOP writing team

5.2. List all relevant SOPs

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

5.3. Format and layout

Each SOP should be given a number and a title that is self explanatory and is easily understood. A unique code number with the format SOP/XX/VV.W

XX - two digit number assigned specifically to the SOP.
VV - version with one digit number identifying the version of the SOP
W is a one digit number identifying the version of SOP with minor changes in the SOP. The number of version should be started from 01 and the W should be started with 0, for example, SOP 01/V1.1 is the SOP number 1 version 1 with one minor revision i.e. V1.1.

Each SOP will be prepared according to the standard template.

5.4. Write and approve new SOP

- A draft will be written by the member secretary/ member of the SOP team
- The draft SOP will be discussed with the other members of the SOP sub- committee members.
- The final version will be passed to the Chair person for review and approval.

5.5. Implement, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date.
- The approved SOPs will be distributed to the EC members and the relevant staff by the *Secretariat.* When 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.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the secretariat of the ethics committee and keep the file in the Ethics Committees office.

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

- 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 there is any change in the regulatory guidelines should use the form (Annex-5) in to make a request.
- 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 made the request of the decision.
- 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).

5.7. Manage and archive superseded SOPs

- Superseded SOPs should be retained and clearly marked "superseded" and archived in the historical file by the *secretariat***.**

6. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describe all activities and action undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.

IEC members	Individuals serving as regular and alternate members on the institute's Ethical Committee. These committees are constituted in accordance with the EC membership requirements set forth in ICH GCP.
SOP Team	A selected committee of the members of NIRRH Ethics Committee and administrative staff who oversee the creation, preparation, review and periodic revision of the institute SOPs.
Master SOP files	An official collection of the institute standard operating procedures (SOP) accessible to all staff, IEC members, auditors and government inspectors as a paper copy with an official stamp on first and last page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered official.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.

7. References

7.1 WHO Operational Guidelines for Ethical Review Committee That Review Biomedical Research (Geneva 2000 www.who.int/tdr/publications/publications/- accessed 11 February 2005)

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

7.4 SOPs Ethics Committee for Research on Human Subjects, Seth G S Medical College and K.E.M. Hospital, Mumbai - August 2013

8. ANNEX

ANNEX 1	List of SOPs	AF/EC/01/01/V1.3
ANNEX 2	Template for SOP	AF/EC/02/01/V1.3
ANNEX 3	Document History	AF/EC/03/01/V1.3
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ANNEX 1 **AF/EC/01/01/V1.3**

LIST OF STANDARD OPERATING PROCEDURES VERSION-3

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ANNEX 2 **AF/EC/02/01/V1.3**

Standard Operating Procedures Template

Name of Ethics Committee *Title: (Title which is self-explanatory and is easily understood)*	*SOP Code: SOP/xx/vv.w* *SOP Code: SOP/xx/vv.w* Page: … of ….

Title:

SOP Code: *SOP/xx/vv.w*

Effective date: dd/mm/yyyy

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ANNEX 2 **AF/EC/02/01/V1.3**

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 clearly 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. **Glossary** – clarifies uncommon or ambiguous words or phases by explanation.
7. **Reference** – lists sources of the information given in the SOP.
8. **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/EC/03/01/V1.3**

Document History

(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/EC/04/01/V1.3**

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/EC/05/01/V1.3**

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/EC/06/01/V1.3**

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