
Title: Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)

SOP Code: SOP 01/V1 dated 18th February 2017

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committee (IEC), Institute of NephroUrology, Bengaluru. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian laws and relevant, National and International Guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the Institutional Ethics Committee (IEC).

3. Responsibility

It is the responsibility of the Chairperson of the IEC to appoint the SOP Team to formulate the SOPs. The SOP Team shall do this by following the same procedures, format, and coding system when drafting or editing any SOP of the Institutional Ethics Committee.

3.1 Secretariat of the Institutional Ethics Committee will

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed to the IEC members.
- Maintain a record of the investigators to whom SOPs are distributed
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current version of SOPs
- Maintain on file all past SOPs of the IEC
- Assist Chairperson to formulate an SOP Team

3.2 SOP team (will contain Member Secretary and at least two other members) will:

- Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson
- Propose new / modified SOPs as needed
- Select the format and coding system for SOPs
- Draft the SOP in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

3.3 Chairperson of the IEC will:

- Appoint one or more SOP Teams
- Approve the SOPs
- Sign and date the approved SOPs

3.4 IEC members and involved administrative staff will:

- Sign and date the approved SOP when they receive it
- Maintain a file of all SOPs received

4. Flow Chart

No.	Activity	Responsibility
1	Identify the need for new or amending SOP	Any member of IEC, secretariat or administrative staff
2	Appoint one or more SOP Teams	Chairperson
3	List all relevant SOPs	SOP Team
4	Design a format and layout	SOP Team
5	Write and review a new/revised SOP	SOP Team
7	Preparation and submission of final draft	SOP Team
8	Approve a new/revised SOP	Chairperson
9	Ensure implementation, distribute and file all SOPs	IEC members and Secretariat
10	Review and request for a revision of existing SOPs	IEC members/ Administrative staff/ Chairperson
11	Manage current and archive superseded SOPs	Administrative staff

5. Detailed instructions

5.1 Identify the need for new or amending SOP

Any member of the IEC or Secretariat who would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by using the Request for Formulation of new SOP/ Revision of an SOP Form AX 05/SOP01/V1 to make a request. This annexure form is submitted to the IEC Chairperson.

The Chairperson will inform all the IEC members about this request in a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson and designated the task to proceed with the revision process/ formulation process of the SOP. If the IEC members do not agree, no further action will be taken. The Chairperson will inform the person/ IEC member who made the request for modification of the SOP will be informed in writing about the decision.

5.2 Appoint the SOP Team(s)

The Chairperson will constitute an SOP Committee(s) consisting of the member-secretary and two or more members of the IEC who have a thorough understanding of the ethical review process. The SOP writing team will carry out the subsequent steps. (5.3-5.7)

5.3 List all relevant SOPs

- Write down step by step all the procedures of the Institutional Ethics Committee

- Organize, divide and name each process

5.4 Design a 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/Vy** will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP. "V" refers to version of the SOP and "y" will be a number identifying the version. The current version of the SOPs would be the **first one** hence it will be denoted as "V1". The first SOP of the current version would be SOP 01/V1 i.e. it is SOP number 01 with version 1.

Each annexure will be given unique code number with the format **AX pp/SOP xx/Vy**. AX refers to annexure form, pp is a two-digit number identifying the number of the annexure, while xx/Vy refers to the SOP number and its version. For example **AX 01/SOP01/V1** means annexure form number one belonging to the SOP 01/V1.

Each SOP will be prepared according to the standard template in **AX 02/SOP01/V1**. Each page of the SOP will bear the header which will have the effective date i.e. the date of approval of the SOPs. The SOP number will be on the left hand corner while the right hand corner will bear the page number as Page - of total pages. The first page of each SOP document will be signed and dated by the authors, the IEC members who have reviewed the SOPs and the IEC Chairperson and subsequently the SOP will be implemented from that date.

5.5 Write and review a new/revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form **AX 03/SOP01/V1** along with description of the main changes.
- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson.

5.6 Review by Consultation

- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team. After incorporating the suggestions put forth by the SOP team members; a copy of the revised draft SOP will be sent to the Member-Secretary, who will circulate it to all the IEC members.

5.7 Preparation and submission of final draft

- IEC Members will review the revised draft SOP at a special meeting.
- The suggestions that are agreed upon by the IEC members present at the special meeting will be discussed and incorporated in the revised draft SOP and the final draft of the SOP will be formulated.
- The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

5.8 Approve a new / revised SOP

- The final version will be presented to the Chairperson for review and approval.
- The authors, reviewers and the Chairperson sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from where by the SOP will be implemented.

5.9 Ensure Implementation, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date.
- The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement it accordingly.
- The approved SOPs will be distributed to the IEC members according to the distribution list. AX 04/SOP 01/V1.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Secretariat of the IEC in the office of Institutional Ethics Committee.
- When the revised version is distributed, all the IEC members will be requested to destroy the earlier version. One copy of the earlier version will be filed centrally in the file entitled 'Past SOPs of the IEC' by the Secretariat of the IEC in the IEC office.
- The Secretariat will review the SOPs at least once in every 3 years and record the dates of review on the SOP Master file.
- As per the findings and opinion of the Secretariat, the Member-Secretary will inform the Chairperson about the result of review process.
- The Chairperson will inform the IEC members at a regular meeting about the recommendation regarding review of SOPs or about the request for revision in the SOP made by a member. If members agree, the Chairperson will constitute one or more SOP teams as per need to amend/ modify SOPs as per 5.2. The SOP team will write and review SOP as per procedure described in 5.3. The SOPs will be distributed, discussed, approved as per procedure described in 5.7 and 5.8. The SOPs will be implemented, distributed and filed as per 5.9

6. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC 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 functioning, whilst maintaining high standards of Good Clinical Practice.
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IEC members	Individuals serving as regular members of the Institutional Ethics Committee. The Board has been constituted in accordance with the IEC membership requirements set forth in Schedule Y (20 th January 2005 and changed according to amendment in Schedule Y (30 January 2013, 8 th February 2013)
SOP Team	A Team of members selected from the Institutional Ethics Committee including the Member Secretary and at least two more members who oversee the creation, preparation, review and periodic revision of the Institutional Ethics Committee SOPs.
Master SOP files	An official collection of the Standard Operating Procedures (SOPs) of Institutional Ethics Committee accessible to all staff, IEC/ members, auditors and government inspectors as a paper copy with an official stamp and the signature of either member secretary/ chairperson of the IEC on the first and the last page of the SOP booklet. Photocopies made from these official paper versions of the SOP cannot be considered official.
Past SOPs of the IEC	A collection of previous official versions of a SOPs and relevant information regarding changes and all preplanned deviations.
Effective date	The date of approval of the SOPs signed and dated by the Institutional Ethics Committee- Chairperson and subsequently the SOP is implemented from that date.

7. References

- [1] WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2013)
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996. <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st August 2013)
- [3] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st August 2013)
- [4] Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) [http://www.cdsc.nic.in/html/Schedule-Y%20\(Amended%20Version-2005\)%20original.htm](http://www.cdsc.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm) (last accessed 31st August 2013)

8. Annexure

Annexure 1	<i>AX 01/SOP 01/V1</i>	List of SOPs of IEC
Annexure 2	<i>AX 02/SOP 01/V1</i>	Template for Standard Operating Procedures
Annexure 3	<i>AX 03/SOP01/V1</i>	Document History of the SOP
Annexure 4	<i>AX 04/SOP01/V1</i>	Log of the IEC members receiving SOPs
Annexure 5	<i>AX 05/SOP01/V1</i>	Request for Formulation of a new SOP/ revision of an SOP
Annexure 6	<i>AX 06/SOP01/V1</i>	Logs of SOP Recipients

Annexure 1

AX 01/SOP 01/V1

List of SOPs of Institutional Ethics Committee

No	Title of the Standard Operating Procedures (SOPs)	SOP Code
1	Preparation of Standard Operating Procedures (SOPs) for the Institutional Ethics Committee (IEC)	SOP 01/V1
2	Constituting the Institutional Ethics Committee.	SOP 02/V1
3	Confidentiality / Conflict of Interest Agreements	SOP 03/V1
4	Selection and Responsibilities of Independent Consultants	SOP 04/V1
5	Management of Protocol Submissions	SOP 05/V1
6	Initial Review of Submitted Protocol	SOP 06/V1
7	Expedited Review	SOP 07/V1
8	Review of Resubmitted Protocols	SOP 08/V1
9	Review of Amended Protocol/Protocol related documents	SOP 09/V1
10	Continuing Review of Study Protocols	SOP 10/V1
11	Review of Study Completion Reports	SOP 11/V1
12	Protocol Deviation/Non-Compliance/Violation	SOP 12/V1
13	Management of Premature Termination of the Study	SOP 13/V1
14	Review of Serious Adverse Event (SAE) Reports	SOP 14/V1
14(A)	Constituting SAE Subcommittee	SOP 14(A)/V1
15	Site Monitoring Visit	SOP 15/V1
16	Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP 16/V1
17	Conduct of Emergency Meeting	SOP 17/V1
18	Maintenance of Active Project Files	SOP 18/V1
19	Archiving and Retrieving Documents	SOP 19/V1
20	Maintaining Confidentiality of IEC Documents	SOP 20/V1
21	Responding to Research Participant's Request or Complaint	SOP 21/V1
22	Exemption from the Ethics Review for Research Projects	SOP 22/V1
23	Request for Waiver of Written Informed Consent	SOP 23/V1
24	Reviewing proposals involving vulnerable Populations	SOP 24/V1

Annexure 2

AX 02/SOP 01/V1

Template for Standard Operating Procedures

Effective date: aa/bb/cccc	Short Title	Page p of q
SOP xx/Vy		
Institutional Ethics Committee Institute of NephroUrology, Bengaluru-560002		

Title: Title which is self-explanatory and easily understood

SOP Code: SOP xx/Vy
Effective date: aa bb cccc
Authors: xxxxxxxxxx
Reviewed by: xxxxxxxxxx
Approved by: xxxxxxxxxx

Signature with date -----
Signature with date -----
Signature with date -----

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Main Text:

- Purpose:** Summarizes and explains the objectives of the procedure.
- Scope:** States the range of activities that the SOP applies to.
- Responsibility:** Refers to person(s) assigned to perform the activities involved in the SOP
- Flow chart:** Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity
- Detailed instructions:** Describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.
- Glossary:** Clarifies uncommon or ambiguous words or phrases by explanation.
- References:** Lists sources of the information given in the SOP
- 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

Annexure 3

AX 03/SOP 01/V1

Document History of the SOP

Details of superseded SOP

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main change

Annexure 4

AX 04/SOP01/V1

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date

Annexure 5

AX 05/SOP 01/V1

Request for Formulation of new SOP/ Revision of an SOP

This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

<i>SOP xx/Vy</i>	
Title:	
Details of problems or deficiency in the existing SOP	
Need to formulate an entirely new SOP (i.e. SOP not existing previously)	
Identified by:	Date (DD/MM/YYYY):
Discussed in Institutional Ethics Committee Meeting held on:-	
SOP revision required: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Action required: <input type="checkbox"/> New SOP to be formulated <input type="checkbox"/> SOP to be deleted <input type="checkbox"/> SOP to be amended <input type="checkbox"/> No action to be taken <input type="checkbox"/> Any other (Please specify): If no action to be taken, please state reasons	
If action recommended: SOP team:	
[1] Member-Secretary:	[4]
[2]	[5]
[3]	[6]

Date -SOP re-finalized:	
Date -SOP approved:	
Date- SOP becomes effective:	
Signature with date Chairperson, IEC	

Annexure 6

AX 06/SOP 01/V1

Log of SOP recipients

No.	Name of the Recipients	Designation	SOP code number	No. of Copies	Date
1	XXXXXX	XXXXX			
2	XXXXXX	XXXXX			
3	XXXXXX	XXXXX			
4	XXXXXX	XXXXX			
5	XXXXXX	XXXXX			