


TAGORE MEDICAL COLLEGE & HOSPITAL 	Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)		Institutional Ethics Committee
			TMCH/IEC/SOP/23
Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 1 OF 7

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

For Institutional Ethics Committee

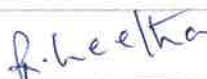


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Issue No : 01
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Copy No : 01/10
**Copy Holder Name
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1. Purpose

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), Tagore Medical College and Hospital Ethics Committee. 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
- 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 a file of all past SOPs of the IEC
- Assist Chairperson to formulate an SOP Team

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Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 3 OF 7

3.2 SOP team (will contain Member Secretary and at least one other member) 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/modify 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

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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
6	Review by Consultation	SOP Team
7	Preparation and submission of final draft	SOP Team
8	Approve a new/revised SOP	Chairperson
9	Ensure implementation, and file all SOPs	IEC members and Secretariat
10	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.
- The SOPs will be updated regularly at the interval of 2 years or if there are major changes whichever is earlier.
- 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.

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5.2 Appoint the SOP Team(s)

The Chairperson will constitute an SOP Committee(s) consisting of the member-secretary and one 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** will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based.
- Each SOP will be prepared according to the standard template and each page of the SOP will bear the header which will have the effective date i.e. the date of approval and validity of the SOPs. The SOP number will be on the right-side corner while the bottom of page will bear the signatures of the members of SOP team,

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.

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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 to invite suggestion.

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 footer 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 and file all SOPs

- The approved SOPs will be implemented from the effective date.

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- The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement it accordingly.
- 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 implemented 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 two 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.

5.10 Manage current and archive superseded SOPs

Old SOPs should be retained and archived in a file by the secretariat.

6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22nd October 2020).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22nd October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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