
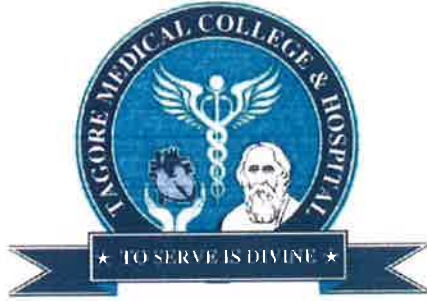


TAGORE MEDICAL COLLEGE AND HOSPITAL 	Receipt, review and decision making of proposals		Institutional Ethics Committee
			TMCH/IEC/SOP/3
Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 1 OF 6

Receipt, review and decision making of proposals

For Institutional Ethics Committee




Tagore Medical College and Hospital




Melakkottaiyur, Rathinamangalam, Chennai-127

Ph: 044-30101111

Issue No : 01
Issue Date : 02.11.2020
Copy No : 01/10
**Copy Holder Name
and Designation** : Dr. R. Geetha, Member Secretary, IEC

Prepared By	Reviewed By	Approved By
 Dr. R. Geetha Member secretary of IEC	 Dr. I. Kannan Member of IEC	 Dr. S. Seethalakshmi Chairperson of IEC

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Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 2 OF 6

1. Purpose

This SOP describes how the Tagore Medical College and Hospital - Ethics Committee will review the initially submitted project proposal for approval by the Ethics Committee.

2. Scope



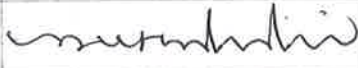
This SOP applies to the assessment of all protocols submitted for review and approval from the IEC.


3. Responsibility

It is the responsibility of the Assigned Reviewer to check the contents of project for their suitability as per the Study Assessment Form and Project Review Form. Assigned reviewer can mark their comments in the forms and sent the same to the EC secretariat 2 days prior to the Ethics committee meeting or within 1 week span when the document is to be reviewed by expedited procedure.

4. Flow chart

Activity	Responsibility
Review of the protocol with associated documents and communicating the comments/suggestions to the ethics secretariat using Study assessment form duly signed & dated	Primary reviewers
Compilation of the comments given by primary reviewers	Secretariat and Member Secretary
Place the study proposal in the IEC meeting	Secretariat and Member Secretary

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Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 3 OF 6

for consideration for approval	
Record the IEC's Decision	IEC Secretariat

5. Detailed instructions

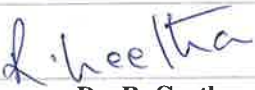


5.1 Placing the proposal before the Ethics Committee Meeting


Member Secretary will provide brief summary and compiled comments of Primary Reviewers. Any additional comments will be provided by primary reviewers followed by the chairperson inviting other members for their comments on the relevance/ deficiencies of the protocol, if any. The Member Secretary and reviewers will ensure that the comments given by the SRC/SAC are included in the protocol. The Principal Investigator/Co- Investigator will be requested to provide clarifications on the study protocol, if required. The Member Secretary (assisted by the Secretarial staff) shall record the discussions and minute it.

5.2 Decision-making on submitted protocols.

The EC members will discuss and clarify the comments and suggestions. The Member secretary (assisted by the Secretarial staff) shall record the discussions and minute it.

Member(s) of the committee who is/are listed as investigator(s) on a research proposal and having conflict of interest shall declare conflict of interest and will not vote on the proposal and will opt out from all deliberations on the proposal by leaving the meeting room. He/ she can participate in the discussion when PI/ Co-investigator is called for providing clarifications. The said member can participate in discussion on all other matters discussed in the meeting.

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An investigator or study team member invited for the meeting will not vote or participate in the decision-making procedures of the committee.

An independent consultant invited for the meeting to provide opinion will not participate in the decision-making procedures of the committee. He/ she is required to provide comments in writing (sent as email/ hard copy)

Specific patient groups invited for the meeting will not participate in the decision-making procedures of the committee. *Please include what their role in participation would be.*

- The decision on the project will be recorded as follows:

o *Approved without change*

o *Minor changes suggested/ clarifications on minor issues sought: Answers to be reviewed by Member- Secretary*




o *Minor changes suggested/ clarifications on minor issues sought: Answers to be reviewed by Member- Secretary, and one/ more primary reviewer(s)*


o *Major changes suggested/ clarifications on major issues sought: Answers to be reviewed by Member- Secretary and one/ more primary reviewer(s)*

o *Major changes suggested/ clarifications on major issues sought: PI's response to be reviewed at the next full-board meeting.*

o *Disapproved*

- If the EC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the study can be initiated.
- If the EC decision is minor modification for expedited review, it implies that the items noted at the convened meeting will be reviewed through expedited review process.
- If the EC decision is major modification for full board, the proposal will have to be submitted for the full board meeting.

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Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 5 OF 6

- If the EC decides to disapprove the protocol, it should give reasons for the same and principal investigator should be asked to respond with justification for reconsideration of the protocol.
- If the study is approved, the Committee will determine the frequency of continuing review for each protocol. Usually, approval is given for one year.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the EC members and minute it.



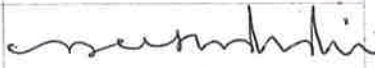
It should also be recorded if the decision needs to be taken at the next full board meeting or can be communicated earlier, based on the assessment by designated authorities. The decision if taken before the next EC meeting, should be put on the agenda of the next meeting and conveyed to the Committee at its next meeting.


5.3 Final communication of the Ethics Committee decision taken on the project to the Principal Investigator

The Secretariat will prepare minutes indicating a decision of the EC meeting on submitted protocol. The minutes will be circulated to all members for approval. Following this the Chairperson and the Member Secretary will sign the minutes.

The minutes will then be given to the PIs mentioning

- Project No. Project title, Date
- Name of the PI
- Date of the meeting when the project is placed before the meeting and approved and version numbers of the project.
- The Secretariat will hand over the minutes within 15 working days without disclosing the names of primary reviewers.

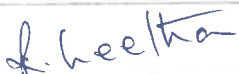


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- The PI will be asked to make the necessary corrections in the project proposal, if required and resubmit it to the ethics secretariat for consideration of the Ethics Committee.
- Principal Investigator will be asked to respond to the comments given through the minutes within 90 days of the receipt of the letter by the investigator. In the absence of any response, the project will be declared closed for the EC office records.
- The approval letter will be signed by Chairperson and Member Secretary and Secretariat will send it to the Principal Investigator. In cases when the Member Secretary is unavailable for the meeting, or he/she is the PI on the project, then the Alternate Member Secretary will sign the letter in his/her place. The approval will be provided only after all requirements are fulfilled including translated PIS and ICD.

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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