


TAGORE MEDICAL COLLEGE AND HOSPITAL 	Review of protocol amendments		Institutional Ethics Committee
			TMCH/IEC/SOP/10
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Review of protocol amendments

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. L Kannan Member of IEC	Dr. S. Seethalakshmi Chairperson of IEC

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how amended protocol/ protocol related documents are managed and reviewed by the Institutional Ethics Committee (IEC).

2. Scope




This SOP applies to previously approved study protocols but later being amended and submitted for approval to the IEC. Amendments made to protocols will not be implemented until reviewed and approved by the IEC.


3. Responsibility

It is the responsibility of the IEC Secretariat to manage protocol amendments. The Member Secretary/ Chairperson will determine whether the proposed protocol amendment(s) is minor or major in nature. Minor amendments would undergo review by the Member Secretary/Chairperson in expedited manner and will be informed in full board. If the amendment is major it will undergo review by primary reviewers and be discussed in full board.

4. Flow chart

Activity	Responsibility
Receive amended protocol package, check contents, ensure completeness of the documents submitted and distribution of amended protocol and study-related documents	IEC Secretariat

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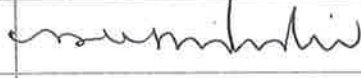
Review the amended protocol and related documents	IEC Members/Member Secretary/Chairperson
Written communication of the IEC decision to investigator	Member Secretary


5. Detailed instructions

5.1 Receive amended protocol package, check contents, ensure completeness of the documents submitted and distribution of protocol and study-related documents

a. Receive amended protocol package, check contents, ensure completeness of the documents:

- The amendment package (hard and soft copy) forwarded by the Principal Investigator will be received by the Secretariat. The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator on previously approved Protocol/Protocol related documents.
- The request form should: state/describe the amendment and provide the reason for the amendment.
- Impact of the amendment on present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)
- The Administrative Officer will confirm that the:
 - amended version of the protocol and related documents are present
 - Changes or modifications in the amended version are highlighted.

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- The Secretariat will check for completeness of the contents of protocol amendment submission package and inform the Principal Investigator to submit the required documents at the earliest, if any of the documents are missing / incomplete.

b. distribution of protocol and study-related documents

- After receipt of the amendment package, the Secretariat will forward the amendment to the Member Secretary/ Chairperson.
- The Secretariat will send the request for amendment and the protocol and related documents to the Member Secretary / Chairperson within 7 working days of receipt of the package with the Protocol Amendment Assessment Form.
- The member secretary or chairperson will categorize the amendments as minor or major amendment as per section 5.2.




5.2 Review the amended protocol and related documents


For Minor amendment

The Minor amendments of the protocol and related documents will be reviewed by either member secretary or chairperson.

For Major amendment




The protocol and related documents will be reviewed by either one / two designated primary reviewers or after review by the designated primary reviewers will be discussed in the upcoming full board meeting. In case the decision is to discuss the amendment at the full board meeting, the Secretary /primary reviewer will present a brief oral summary of the study design and the comments of the primary reviewer /Chairperson in the IEC Full Board meeting.


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Protocol Amendment Review Process

- The primary reviewers will review the amended documents and assess the change in risk benefit ratio and impact of the amendment (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)
- Primary reviewers will send the comments to the member secretary
- Following aspects of the Protocol amendment which may include but is not limited to:
 - Change in study design
 - additional treatments or the deletion of treatments
 - Changes in inclusion/exclusion criteria.
 - change in method of dosage formulation, such as, oral changed to intravenous
 - a significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)
 - a significant decrease or increase in dosage amount
 - Change in risk/benefit ratio
- The final decision regarding the amendments shall include one of the following:
 - If the IEC decision is 'Approved', it implies the approval of the amendment as it is presented with no modifications and the letter of permission for amendment can be issued to the Principal Investigator.
 - If the IEC decision is 'Approved with minor modification, the IEC Chairperson may
 - authorize the member Secretary to issue a recommendation letter to the Principal Investigator and if response from the PI found satisfactory to decide if letter of permission can be issued to the Principal Investigator.
 - If the IEC decision is 'Approved with major modification, the IEC Chairperson may

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- authorize the Primary reviewer + secretary to determine the review of the amendments which may or may not be discussed in next full board meeting depending on the comments of the reviewers. Member Secretary will issue a recommendation letter to the Principal Investigator and if response from the PI found satisfactory to decide if letter of permission can be issued to the Principal Investigator.

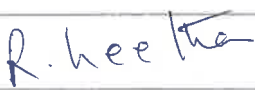


If the IEC decision is Disapproved after the member secretary / chairperson / designated IEC members / Full board review the decision will be communicated with the PI giving reasons for disapproval.

5.3 Written communication of the IEC decision to investigator

- The decision will be communicated to the PI within 14 days and for the amendments which will be discussed in the full board meeting the decision will be communicated within 14 days of the meeting.
- The Secretariat will record the decision reached on the proposed amendment in the minutes of the meeting.

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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