


TAGORE MEDICAL COLLEGE AND HOSPITAL 	Continuing Review of Study Protocols		Institutional Ethics Committee
			TMCH/IEC/SOP/4
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Continuing Review of Study Protocols

For Institutional Ethics Committee




Tagore Medical College and Hospital




Melakkottaiyur, Rathinamangalam, Chennai-127

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

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Dr. R. Geetha Member secretary of IEC	Dr. I. Kannan Member of IEC	Dr. S. Seethalakshmi Chairperson of IEC

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1. Purpose

The purpose of this Standard Operating Procedure is to describe how continuing reviews of previously approved protocols are managed by the Institutional Ethics Committee (IEC). The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants.



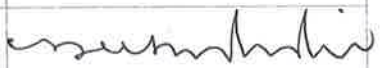
2. Scope


This SOP applies to conducting any continuing review of study protocols involving research participants at intervals appropriate to the degree of risk. All the projects approved by the Institutional Ethics Committee will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the IEC Secretariat to remind the IEC and the principal investigators regarding study protocols that should be continuously reviewed. All the approved protocols will be reviewed annually (at least once a year). The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IEC meeting wherein the project is finally approved or can be taken subsequently based on the SAE reports, monitoring reports, adequacy documentation procedures followed by the investigators or new safety data received.

The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants.

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4, Flow chart

No.	Activity	Responsibility
1	Determine the date of continuing review and Notify the Principal Investigator or study team	IEC Secretariat
2.	Manage continuing review package upon receipt and distribute to member secretary/chairperson	IEC Secretariat
3.	Assign reviewers and review the annexure/ related documents of continuing review	Chairperson /Member Secretary/ IEC Members
4.	Written communication of the IEC decision to investigator	IEC Secretariat

5. Detailed Instructions

5.1. Determine the date of continuing review and Notify the Principal Investigator or study team

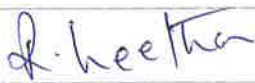


a. Determining the date of continuing review


The Administrative Officer will look through the document archives/master chart of projects approved by the IEC for the due date of continuing reviews.

The Secretariat will plan for continuing review of annual progress reports to be reviewed as close as possible to the due date or the anniversary of the effective date (date of original approval) of the protocol.

b. Notifying the Principal Investigator or the study team

If the Principal Investigator fails to submit the Continuing review report within one month of the due date (i.e. 11th months from the date of approval, unless specified otherwise), the IEC

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secretariat will send a reminder as per the format mentioned in within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to

a) A letter of reprimanding the Investigator.

Not reviewing future projects from the PI for a specified period of time / till the submission of status report of the previous study.



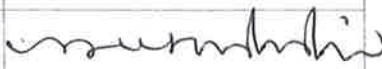
b) A letter asking the Investigator to put recruitment of new participants on hold.


5.2 Managing the continuing review package upon receipt.

The Secretariat will receive a package (soft and hard copy) submitted by the Study Team of continuing review for each approved protocol. The Secretariat will make sure that the contents of the package include the following documents:

Continuing Review Application Form duly filled with an explanation for any “yes” (ticked on the Continuing Review Application Form answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. have to be discussed in the attached narrative.

The Secretariat will check for complete information and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form. The Secretariat will forward the continuing review report to the Member Secretary/ Chairperson.

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5.3 Assign reviewers and review the annexure/ related documents of continuing review



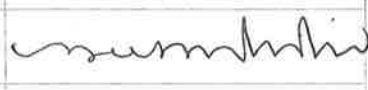
The Chairperson /Member Secretary will review the Continuing Review Application Form. The Chairperson / member secretary can designate one/two IEC members to review the Study report and related documents and inform the decision to the other IEC members at the next full board meeting.


Review of Continuing Review Application

The Continuing review submission may undergo expedited review or full board review as deemed appropriate by the IEC Chairperson/ Member Secretary.

The IEC Chairperson/ Member Secretary/ Member/s could reach one of the following decisions after review:

1. Noted: The IEC approves the continuation of the above-mentioned project without any Modifications.
2. Modifications recommended: Protocols that have been suggested modifications by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within one month for re-review.
3. The project cannot be continued: The reasons for discontinuation of the project will be mentioned in the letter notifying the decision to the Principal Investigator.
4. The decision will also include any significant findings that have arisen during review process and this will be communicated to Principal Investigator. It is the responsibility of Principal Investigator to provide this information to the participants and once done submit the report to IEC.

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5.4 Written communication of the IEC decision to investigator

The decision will be communicated to the PI within 14 days and for the continuing review reports 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 continuing review report 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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