	Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu **Resubmitted Protocols**	SOP 05-D/V5 Effective from 1st Aug 2017, Valid up to 30th July 2019

Title: **Review of Resubmitted Protocols**

SOP Code: **SOP 05-D/V5 dated 26th July 2017**

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how Institutional Ethics Committee (IEC) manages study protocols and related documents resubmitted after initial review.

2. Scope

This SOP applies to study protocols that have been resubmitted to the IEC with the Principal Investigator responding to clarifications and modifications sought and comments made by the IEC during initial review.

3. Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC for reconsideration of a protocol; which is previously reviewed earlier with recommendations from IEC for some changes.

A re-submitted protocol may be reviewed by either the Chairperson or two or more IEC members designated by the Chairperson/ Member secretary, or all the IEC members as per IEC decision determined by the IEC at the time of the initial review of the project during the full board IEC meeting. This information can be found on the IEC Decision Form (*AX 01/SOP 05-A/V5*).

4. Flow chart

No.	Activity	Responsibility
1	Receive resubmitted protocol package, check contents, ensure completeness of the documents submitted and distribution of protocol and study-related documents	IEC Secretariat
2	Review the revised protocol	IEC Members/Member Secretary/ Chairperson
3	Written communication of the IEC decision to investigator	IEC Secretariat

5. Detailed instructions

5.1 Receipt of resubmitted protocol package and its distribution

- The Secretariat will verify if the principal investigator has forwarded the reply within 180 days of receipt of the letter of comments by the IEC.
- The Secretariat will check the resubmitted protocol packages (hard and soft copy) for the following items
  - ✓ Reply to the IEC letter of comments with covering letter (signed and dated by PI), query reply in question-answers format.

- ✓ Revised version of protocol and/ or the informed consent document and /or any other related documents such as, case report forms, diary sheets, etc are included as part of the package with the changes made to the documents highlighted and with appropriate version number and date on each page of the document.
- ✓ Additional documents sought during initial review

- If above items are not submitted the Principal Investigator will be told to submit the complete package along with all the required documents.
- The Secretariat will refer to the IEC Decision Form *AX 01/SOP 05-A/V5* on the given protocol and distribute this package containing the reply to the query letter, revised protocol and related documents for resubmitted protocol to the Member Secretary

For Minor modifications

The protocol land related documents will be reviewed by either member secretary or one / two designated primary reviewers as per decision taken during initial review.

For Major modifications

The protocol land 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 as per decision taken during initial review. In case the decision is to discuss the revised protocol at the full board meeting, the Primary reviewer / member Secretary will present a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Board meeting.

5.2 Review the revised protocol to be carried out by IEC member/ Member Secretary/ Chairperson:

- The IEC member/ Member Secretary/ Chairperson will refer to the query letter/ comments as guidance for the review and consider whether the recommendations of the IEC have been followed or adequately responded to. The primary reviewer will also check for completeness of protocol and related documents as per requirements. The designated primary reviewers should complete the review process within seven / eight days
- The IEC member/ Member Secretary/ Chairperson will make further comments where appropriate
- The final decision regarding the query reply shall include one of the following:
  - ✓ If the IEC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the letter of permission can be issued to the Principal Investigator.
  - ✓ If the IEC decision is 'Approved with minor modification, the IEC Chairperson may authorize the Secretary/Primary reviewer + secretary to determine if the response and changes are satisfactory and 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 authorize the Primary reviewer + secretary to review the responses which may or may not be

discussed in next full board meeting depending on the comments of the reviewers. If the response and changes are approved in the full board, letter of permission can be issued to the Principal Investigator.

5.3 Written communication of the IEC decision.

The decision will be communicated to the PI within 14 days and for the projects which will be discussed in the full board meeting the decision will be communicated within 14 days of the meeting. Response from the PI to the IEC communication is expected within 180 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records.

- ✓ The Secretariat will record the decision reached on the response in the minutes of the meeting.

6. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - *www.who.int/tdr/publications/publications/* (last accessed 31st July 2017)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-*http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st July 2017)