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|  | Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu | SOP 06/V5 Effective from 1st Aug 2017, Valid up to 30th July 2019 |
| | Review of Amended protocol/ Protocol related documents | |

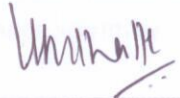

Title: Review of Amended protocol/ Protocol related documents

SOP Code: SOP 06/V5 dated 26th July 2017

Authors:

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Reviewed by:

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| Dr. Urmila Thatte (Member, IEC - I) |  |
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Approved by:

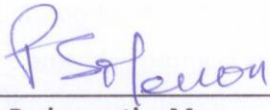
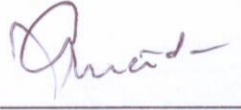

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|  Dr. Padmavathy Menon, Chairperson, IEC - I (Signature with Date) |  Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date) |
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1. Purpose

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

| No. | Activity | Responsibility |
|------------|---|---|
| 1 | Receive amended protocol package, check contents, ensure completeness of the documents submitted and distribution of amended protocol and study-related documents | IEC Secretariat |
| 2 | Review the amended protocol and related documents | IEC Members/Member Secretary/ Chairperson |
| 3 | 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 as per the form AX 01/SOP 06/V5.

- The request form should:
 - ✓ state/describe the amendment
 - ✓ provide the reason for the amendment

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- ✓ 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.
 - 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 AX 01/SOP 06/V5.
 - The member secretary or chairperson will categorized 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.

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:
 - a. Change in study design
 - b. additional treatments or the deletion of treatments
 - c. Changes in inclusion/exclusion criteria.
 - d. change in method of dosage formulation, such as, oral changed to intravenous

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- e. 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)
- f. a significant decrease or increase in dosage amount
- g. 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 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. Glossary

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| Amendment protocol package | A package of the amended parts and related documents of the protocol, previously approved by the IEC. In the course of the study, the PI may decide to make changes in the protocol. |
| Minor protocol amendments | Minor amendments are those that do not increase the risk or decrease the potential benefit to the subjects |
| Major protocol amendments | Major amendments are those that adversely affect the risk benefit ratio of the study or specifically increase the risk to the participants of the study |

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7. 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)
- [3] Code of Federal Regulation (CFR), 21 §56.110, the United States of America, 1998.

8. Annexure


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|------------|-----------------|--|
| ANNEXURE 1 | AX 01/SOP 06/V5 | Protocol Amendment Request and Assessment Form |
| ANNEXURE 2 | AX 02/SOP 06/V5 | Project Amendment/Document Amendment Approval letter |

Annexure 1

AX 01/SOP 06/V5

Protocol / Protocol related documents Amendment Request and Assessment Form

| | |
|---|-------------------|
| IEC Protocol Number: | |
| Protocol Title: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> | |
| Principal Investigator and Department: <hr/> <hr/> | |
| Approved date: | No. of amendment: |
| <input type="radio"/> State/describe the amendment :type of document/ part of document amended <hr/> <hr/> <input type="radio"/> Reasons for the amendment <hr/> <hr/> <input type="radio"/> Impact of your amendment on your 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) <hr/> <hr/> <hr/> | |

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Have the changes modifications in the amended versions been highlighted/ underlined?

Yes ☐ No ☐

Name of Principal Investigator: _____

Signature with Date: _____

Annexure 2

AX 02/SOP 06/V5

Protocol Amendment/Document Amendment Approval letter

To

XXXXX (PI)
Department

Ref: - IEC No. Project title

Dear Dr. _____

We have received from you the following document (s).

- 1.
- 2.

At the Institutional Review Board meeting held on _____ the above mentioned documents were reviewed.

After consideration, the IEC has decided to approve:

(a) The aforementioned study-related documents OR

(b) The following documents:

- 1.
- 2.

The members who attended this meeting held on _____ at which the above mentioned document was discussed are listed below.

- 1.
- 2.
- 3.


It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Review Board.

OR

After reviewing the documents, the IEC has decided to approve the aforementioned study-related documents.

Yours truly,

**Signature of Chairperson/ Member Secretary
with Date
IEC**

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Review of Amended Protocol / Protocol Related Documents

Submission of Amended Protocol/ Protocol Related Documents [submit AX 01/SOP 06/V5]

