



**IHEC – MGMCRI SOPs
Review of Resubmitted and Amended Protocols and
Protocol-related Documents**



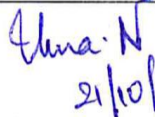

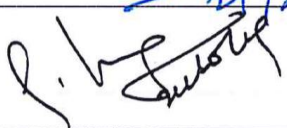
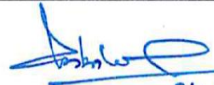


**SOP Code: SOP 09/V2
Effective from 21/10/2019**

Title: Review of Resubmitted and Amended Protocols and Protocol-related Documents

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Effective Date: 21-10-2019

SOP Constitution and Approval:

Prepared by:	Signature and Date:
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Human Ethics Committee (IHEC) manages resubmitted & amended study protocols.

2. Scope

This SOP applies to the review of

- A. Study protocols and related documents that have been **resubmitted** to the IHEC by the Principal Investigator (PI) with clarifications and modifications sought by the IHEC in initial review.
- B. **Amendments** to study protocols and related documents that have been approved earlier.

3. Responsibility

- It is the responsibility of the IHEC Secretariat to ensure the completeness of the documents submitted to the IHEC.
- A re-submitted protocol and related documents may be reviewed by either the Chairperson and two or more IHEC members designated by the Chairperson/Member secretary/Additional Member Secretary, or all the IHEC members as per the IHEC decision determined by the IHEC at the time of the initial review of the project during the full board IHEC meeting. This information would be recorded (during the meeting) on the IHEC Decision Form (AX 03/SOP 7A/V2).
- In the case of an amended study protocol and related documents, Member Secretary/Additional Member Secretary / Chairperson will decide whether the proposed protocol amendment(s) needs to undergo a full board review or expedited review. If the amendment(s) is / are of administrative nature the Member Secretary/Additional Member Secretary/Chairperson can recommend an expedited review, while if the amendment/s relate to participant safety or data capture, it should be recommended for full board review. Additionally, primary reviewers who had reviewed the initial submission maybe asked to review the resubmitted protocol.

4. Detailed instructions

4.A] For resubmitted protocols

4A.1 Receipt of resubmitted protocol and its distribution

- The Secretariat will verify if the PI has replied to IHEC queries within 6 weeks of receipt of the letter of comments by the IHEC.



- The Secretariat will check the resubmitted protocol & related documents (hard and soft copy) for the following items
 - Reply to the IHEC letter of comments
 - 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 submitted with the changes made to the documents either underlined or highlighted.
- The Secretariat will refer to the IHEC Decision Form (AX 03/SOP 7A/V2) on the given protocol and distribute the documents containing the reply to the query letter, revised protocol and related documents along with Assessment Form for resubmitted protocol to
 - Member Secretary/Additional Member Secretary: for summarizing and including it on the agenda for full board discussion in the forthcoming meeting if the decision on the protocol was ‘to be discussed at full board’
 - Designated IHEC member: if decision on protocol was ‘to be reviewed by two or more IHEC members’.
 - Chairperson/Member Secretary/Additional Member Secretary: if the decision on the protocol was ‘Approved with recommendations subject to review by Chairperson/Member Secretary/Additional Member Secretary only’ as per IHEC Decision Form.

4A.2. Review of revised protocol by IHEC member/ Member Secretary/Additional Member Secretary /Chairperson:

- IHEC member/ Member Secretary/Additional Member Secretary / Chairperson will refer to query letter/ comments as guidance for review and consider whether recommendations of IHEC have been followed or adequately responded to.
- IHEC member/ Member Secretary/Additional Member Secretary / Chairperson will make further comments where appropriate, in the Assessment Form for resubmitted protocol AX 01/SOP 09/V2.
- Secretariat will retrieve the Assessment Form for resubmitted protocol AX 01/SOP 09/V2 from the members/Member Secretary/Additional Member Secretary /Chairperson.



- In case the decision is to discuss the revised protocol at the full board meeting, Member Secretary/Additional Member Secretary will present a brief oral summary of the study design and the comments of the IHEC members/Chairperson in the IHEC Full Board meeting.
- Chairperson shall entertain discussion on the protocol revision from all the IHEC members.
- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:
 - a) Approved
 - b) Minor modifications: Goes to Member Secretary/Additional Member Secretary to post to information to Full board
 - c) Major modification: Goes to full board.
 - d) Disapproved giving reasons for disapproval
 - e) Deferment pending further reference by the IHEC members.
 - f) Suspension or termination of an ongoing study.
- In case the revised protocol is already approved through expedited review, the decision is informed to the members at the full board meeting.

4.B| For amended protocols

4B.1 Receipt of protocol for amendments

- The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat and verified.
- 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 02/SOP 09/V2.
- The administrative staff will confirm that the amended version of the protocol and related documents are attached with the application and that the changes or modifications in the protocol are underlined or highlighted in the amended version and sent to primary reviewer for approval.

4B2. Notify Member Secretary/Additional Member Secretary

- The Secretariat will inform the Member Secretary/Additional Member Secretary of receipt of the protocol amendment



4B3. Determine whether full review or review by designated members.

- After review of the materials, the Member Secretary/Additional Member Secretary will determine whether the protocol requires a full board review or expedited review. The Chairperson/Member Secretary/Additional Member Secretary will indicate this decision on the Protocol Amendment Assessment Form AX 02/SOP 09/V2.
- The amended protocol/ protocol related document will require Full Board review if any of the following criteria are met:

The Protocol amendment changes the risk-benefit assessment such as

- a 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
 - 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)
- For regulatory studies, a protocol amendment with above changes would require DCGI approval
 - For expedited review, Form AX 02/SOP 09/V2 will be used to nominate members by the Chairperson/ Member Secretary/Additional Member Secretary.

4B4. Distribution to IHEC members

- The following documents will be distributed to the designated IHEC members as per the decision regarding review
 - The amendment's revision documents to clearly identify each change.
 - Protocol Amendment Assessment Form AX 02/SOP 09/V2.
- Whenever the decision is Full Board review, the Secretariat shall summarize the points for discussion regarding the amended protocol/protocol related documents and shall place the protocol amendment request on the agenda for discussion at the next convened meeting.



4B5. Protocol Amendment Review Process

- IHEC member will review the amended documents and write his/her comments in the form - AX 01/SOP 09/V2.
- Reviewer may request secretariat to keep the documents for full board discussion after review.
- IHEC members performing the review must sign and date the form i.e. AX 02/SOP 09/V2 and return this to the Secretariat after the review.

4B6. IHEC Decision on Amended Protocols

- In case the project is kept for full board review, the Member Secretary/Additional Member Secretary / designated member will present a brief oral summary of the study design and read the comments on the amended protocol/ protocol related documents in the meeting.
- The decision by the designated reviewers may be
 - Approved
 - Disapproved
 - Suggested Recommendation
 - Next full board discussion
- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:
 - Approve the protocol amendment
 - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IHEC review/ IHEC review.
 - Not approve the amendment request, stating the reason – but allow the study to continue as previously approved.
 - Suspend the study, until further information is obtained



4B7. Recording of the decision

- This IHEC decision will be recorded by the Secretariat in the IHEC Decision Form.

4B8. Communication of the Decision to the Principal Investigator

- If the IHEC approves the protocol/ informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter i.e. AX 03/SOP 09/V2 to the Principal Investigator (PI) within 14 working days of the meeting. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 working days of the meeting.
- The letter of comments sent to the investigator shall state that the reply to the letter is expected within 6 weeks of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IHEC office records.
- The Member Secretary/Additional Member Secretary shall inform other members about the decision taken on the amended document/s at the next full board meeting.

5. Reference to other applicable SOPs

- SOP 7A/V2 – Full-Board Review of Research Study Protocols
- SOP 7B/V2 – Expedited Review of research Study Protocols

6. Glossary

Amendment protocol package	A package of the amended parts and related documents of the protocol, previously approved by the IHEC. In the course of the study, the PI may decide to make changes in the protocol.
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7. Annexures

Annexure 1: AX 01/SOP 09/V2 - Assessment of resubmitted protocol

Annexure 2: AX 02/SOP 09/V2- Protocol amendment request and assessment form

Annexure 3: AX 03/SOP 09/V2- Protocol Amendment/Document Amendment Approval letter



Annexure 1: AX 01/SOP 09/V2
Assessment of resubmitted protocol

Protocol Number:

Protocol Title:

Number of review	2 nd Review	3 rd Review	4 th Review
Principal Investigator:			Department:
Date of Initial Review by IHEC:		Date of Last Review:	
The IHEC Decision recorded in the meeting minutes: (meeting held on _____) _____			

Opinion of the reviewer:

Revision or Modification according to the recommendation	Yes	No: Explain:
Approved	Yes	No
If disapproved, reasons for disapproval		
Further revision or modification required		
To be discussed at the forthcoming full board meeting		
Any Other		

Name of the Reviewer: 1)

Signature:

Date:

Name of the Reviewer: 2)

Signature:

Date:

Final Decision: Approved Yes / No

If disapproved, reasons for disapproval:

Further revision or modification required / Resubmission:

Any other reason(s):

Signature of the Member Secretary/Additional Member Secretary/ Chairperson:

Date:



Annexure 2: AX02/SOP 09/V2

**Protocol /Protocol related documents Amendment Request and Assessment
Form**

MGMCRI-IHEC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

- 1. Date of EC Approval: _____ Date of Start of study: _____
- 2. Details of amendment(s)

S. No	Existing Provision	Proposed Amendment	Reason	Location in the protocol / ICD <i>(Location implies page number in the ICD/protocol where the amendment is proposed.)</i>

3. Impact on benefit-risk analysis Yes No

If yes, describe in brief:

.....
.....

4. Is any re-consent necessary? Yes No

If yes, have necessary changes been made in the informed consent? Yes No

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants)

Full review by EC (There is an increased alteration in the risk to participants)

6. Version number of amended Protocol/Investigator’s brochure/ICD:

Signature of PI with date:



Annexure 3: AX03/SOP 09/V2

Protocol Amendment/Document Amendment Approval letter

To

Name of PI

Department

Ref: - IHEC No. Project title

Dear Dr. _____

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

- 1.
- 2.

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

After consideration, the IHEC 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.

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.

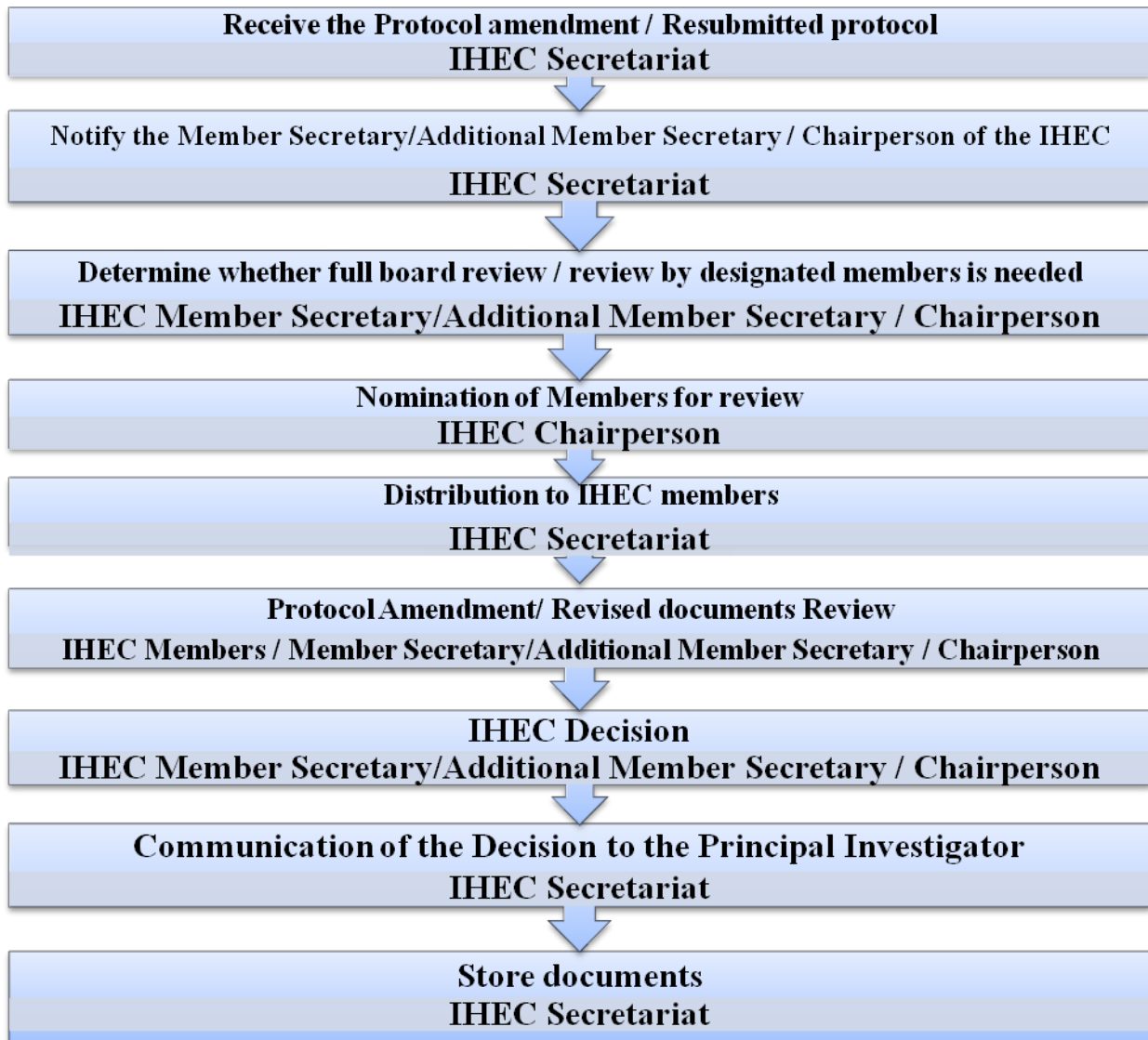
OR

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

Yours truly,
(Signature of Member Secretary/Additional
Member Secretary with Date)



8. Flowchart



9. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*