



SOP 09	 <p style="text-align: center;">Sri MANAKULA  VINAYAGAR Medical college and Hospital</p>	
SOP code: SOP 09/ V4	<i>Review of Resubmitted and Amended Protocols and Protocol-related Document</i>	Effective Date: 02.01.2024

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

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (EC) 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 EC by the Principal Investigator (PI) with clarifications and modifications sought by the EC in initial review
- B. Amendments to study protocols and related documents that have been approved earlier

3. Responsibility

- It is the responsibility of the EC Secretariat to ensure the completeness of the documents submitted to the EC.
- A re-submitted protocol and related documents may be reviewed by either the Chairman and two or more EC members designated by the Chairman/ Member secretary, or all the EC members as per EC decision determined by the EC at the time of the initial review of the project during the full board EC meeting. This information would be recorded (during the meeting) on the EC Decision Form (AX 03/SOP 7A/V4).
- In the case of an amended study protocol and related documents, The Member Secretary/ Chairman 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/Chairman 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 may be asked to review the resubmitted protocol.



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4. Detailed instructions

AI For resubmitted protocols


4A1. Receipt of resubmitted protocol and its distribution

- The Secretariat will verify if the PI has replied to EC queries within 10 days of receipt of the letter of comments by the EC.
- The Secretariat will check the resubmitted protocol & related documents (hard and soft copy) for the following items
 - Reply to the EC 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 EC Decision Form (*AX 03/SOP 7A/V4*) 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
 - The 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’
 - The Member Secretary summarizing and submit to Chairman for Approval if the decision on the protocol was ‘Approved with minor revisions / recommendations as per SMVMCH-EC Decision Form.

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4A2. Review of revised protocol by EC member/ Member Secretary/Chairman:

- The EC member/ Member Secretary/ Chairman will refer to the query letter/ comments as guidance for the review and consider whether the recommendations of the EC have been followed or adequately responded to.
- The EC member/ Member Secretary/ Chairman will make further comments where appropriate, in the Assessment Form for resubmitted protocol *AX 01/SOP 09/V4*.
- The Secretariat will retrieve the Assessment Form for resubmitted protocol *AX 01/SOP 09/V4* from the members/Member Secretary/Chairman.
- In case the decision is to discuss the revised protocol at the full board meeting, the Member Secretary will present a brief oral summary of the study design and the comments of the EC members/Chairman in the EC Full Board meeting.
- The Chairman shall entertain discussion on the protocol revision from all the EC 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:
 - SMVMCH-EC can give one of the following decisions:
 - ✓ Approved – with or without suggestions or comments;
 - ✓ Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
 - ✓ Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/ revoking of permission.
- In case the revised protocol is already approved through expedited review, the decision is informed to the members at the full board meeting.

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B/ For amended protocols

4B1. 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/V4*.
- 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.

4B2. Notify Member Secretary


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

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

- After review of the materials, the Chairman / Member Secretary will determine whether the protocol requires a full board review or expedited review. The Chairman/Member Secretary will indicate this decision on the Protocol Amendment Assessment Form *AX 02/SOP 09/V4*
- 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
- 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)

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- For regulatory studies, a protocol amendment with above changes would require DCGI approval
- For expedited review, members will be nominated by the Chairman/ Member Secretary.

4B4. Distribution to EC members


- The following documents will be distributed to the designated EC members as per the decision regarding review
 - The amendment's revision documents to clearly identify each change.
 - Protocol Amendment Assessment Form
- 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

- The EC member will review the amended documents and write his/her comments in the form - AX 02/SOP 09/V4.
- The reviewer may request the secretariat to keep the documents for full board discussion after review.
- The EC members performing the review must sign and date it and return it to the Secretariat after the review.

4B6. EC Decision on Amended Protocols

- In case the project is kept for full board review, the Member Secretary will present a brief oral summary of the study design and read the comments on the amended protocol/ protocol related documents in the meeting.

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4B7. Recording of the decision


- This EC decision will be recorded by the Member Secretary in the EC Decision Form.

4B8. Communication of the Decision to the Principal Investigator

- If the EC 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/V4 to the Principal Investigator (PI) within 7 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 10 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the EC office records.
- The 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/V4 – Initial Full-Board Review of Research Study Protocols
- SOP 7B/V4 – Expedited Review of Research Study Protocols

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6. Annexures

Annexure 1 *AX 01/SOP 09/V4* - Assessment of resubmitted protocol


Annexure 2 *AX 02/SOP 09/V4* - Notification form for Amendments in protocol

Annexure 3 *AX 03/SOP 09/V4* - Protocol Amendment/Document Amendment Approval letter

Annexure 1: AX 01/SOP 09/V4

Assessment of Resubmitted Protocol

Protocol Number	
Protocol Title:	
Number of review : <input type="checkbox"/> 2 nd Review <input type="checkbox"/> 3 rd Review <input type="checkbox"/> 4 th Review	
Principal Investigator:	Department:
Date of Initial Review by EC:	Date of Last Review:
The EC Decision recorded in the meeting minutes: (meeting held on _____)	

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Opinion of the reviewer:

Revision or Modification according to the recommendation	<input type="checkbox"/> Yes <input type="checkbox"/> No: Explain: _____
Approved	<input type="checkbox"/> Yes <input type="checkbox"/> 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

Signature of the Member Secretary/ Chairman: _____

Date: _____

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Annexure 02/SOP-9/V4

Notification form for Amendments in protocol

SMVMCH-EC 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:

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Annexure 3: AX 03/SOP 09/V4

Protocol Amendment/Document Amendment Approval letter

To
XXXXX (PI)
Department

Ref: - EC 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 EC 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.

- 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 EC has decided to approve the aforementioned study-related documents.


Yours truly,

Signature of EC Chairman/ Member Secretary with Date

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
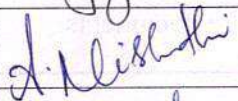
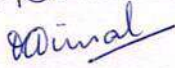

7. Flowchart

No.	Activity	Responsibility
1.	Receive the Protocol amendment / Resubmitted protocol	EC Secretariat
2.	Notify the Member Secretary / Chairman of the EC	EC Secretariat
3.	Determine whether full board review / review by designated members is needed	EC Member Secretary / Chairman
4.	Nomination of Members for review	EC Chairman
5.	Distribution to EC members	EC Secretariat
6.	Protocol Amendment/ Revised documents Review	EC Members / Member Secretary / Chairman
7.	EC Decision	EC Member Secretary / Chairman
8.	Communication of the Decision to the Principal Investigator	EC Secretariat
9.	Store documents	EC Secretariat

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8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: [http:// www.ferci.org/sops/](http://www.ferci.org/sops/)
2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

	Name	Designation	Signature
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	Dr. Nishanthi. A	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. Thiagarajan. T	Chairman	
Issued	Dr. R. N. Kagne	Dean	