

	Institutional Ethics Committee Title: Review of Resubmitted Amended Protocols and Protocol-related Documents	SOP 09/V1 Effective from September 2019 Valid till September 2022
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9.1.Purpose

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

9.2.Scope

This SOP applies to the review of research proposals and related documents that have been resubmitted to the IEC as amended ones by the Principal Investigator (PI) with clarifications and modifications sought by the IEC in initial review.

9.3.Responsibility

- It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC.
- In the case of a research proposal and related documents is/are revised with minor amendments it will undergo expedited review and if they are revised with major amendments they will undergo a full committee review. Additionally, primary reviewers who had reviewed the initial submission may be asked to review the resubmitted proposal and related documents, if any.
- If the amendment(s) is/are of administrative nature an expedited review will be undertaken, while if the amendment/s relate to participant safety or data capture full committee review should be recommended. This information would be recorded (during the meeting) on the IEC Decision Form. .

9.4. Detailed instructions

9.4.1. Receipt of resubmitted protocol and its distribution

- The Secretariat will verify if the PI has replied to IEC queries within 180 days of receipt of the letter of comments by the IEC.
- If PI does not submit the revised
- The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat and verified.

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- The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator.
- The Secretariat will check the resubmitted protocol and related documents (hard and soft copy) for the following items
 - List of point wise reply to the IEC 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 amended proposal and related document will require Full Committee 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)
- For expedited review, the Chairperson/ Member Secretary will use prescribed form.
- The Secretariat will refer to the IEC Decision Form 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 committee review in the forthcoming meeting if the decision on the protocol was ‘to be discussed at full committee meeting’
 - The designated IEC members if the decision on the proposal was ‘to be reviewed by primary reviewers/two or more IEC members.

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- The Chairperson/Member Secretary if the decision on the protocol was ‘Approved with recommendations subject to review by Chairperson/Member Secretary only’ as per IEC Decision Form.

9.4.2. Review of revised protocol 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 IEC member/ Member Secretary/ Chairperson will make further comments where appropriate, in the Assessment Form for resubmitted protocol.
- The Secretariat will retrieve the Assessment Form for resubmitted protocol from the members/Member Secretary/Chairperson.
- In case the decision is to discuss the revised protocol at the full committee meeting, the Member Secretary will present a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Committee meeting.
- The Chairperson shall invite discussion on the protocol revision from all the IEC members.
- The final decision regarding the research project shall be reached by consensus/voting and shall include one of the following:
 - a. Approved
 - b. Further modifications to items noted at the convened meeting and follow-up by the Chairperson/Member Secretary/IEC members after receipt of the requested modifications for placing in the next meeting
 - c. Disapproved giving reasons for disapproval
 - d. Suspend the study, until further information is obtained
- In case the revised protocol is already approved through expedited review, the decision is informed to the members at the full committee meeting.
- The primary reviewer/IEC members performing the review must sign and date the form and return this to the Secretariat after the review.

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9.4.3 Communication of the Decision to the Principal Investigator

- If the IEC approves the protocol/ informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 14 working days of the meeting.
- The decision regarding disapproval (stating reasons) or request for specific modifications 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 stipulated time (within 14 days) and in the absence of any response, the project will be declared closed.
- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full committee meeting.

9.5 Annexures

Annexure 1: AX 1/SOP 09/VI Assessment of Resubmitted Protocol

Annexure 2: AX 2/SOP 09/VI Proposal and/or related documents Amendment Request and Assessment Form

Annexure 3 AX 3/ SOP 09/VI Proposal Amendment/Document Amendment Approval letter

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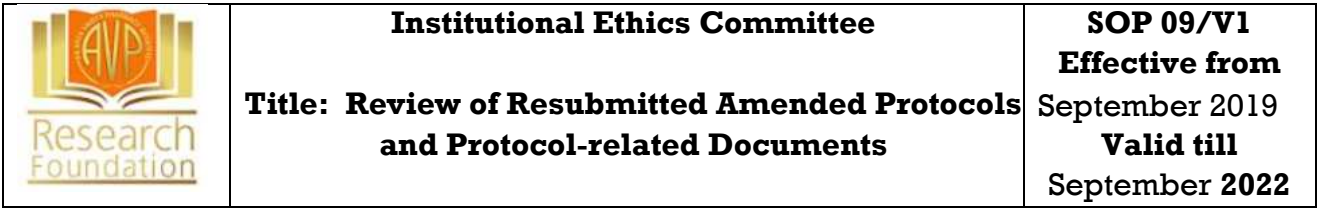
Annexure 1: AX 1/SOP 09/VI

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 IEC:	Date of Last Review:
The IEC Decision recorded in the meeting minutes: (meeting held on _____) _____	
Opinion of the reviewer:	
Approved	Yes No
If disapproved, reasons for disapproval	_____ _____
Further revision or modification required	_ Yes No: Explain: _____ _____ _____
To be discussed at the forthcoming full committee meeting	_____ _____
Any Other	_____ _____

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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 for Resubmission Any Other	
Signature of the Member Secretary/ Chairperson: _____ Date: _____	



Proposal and/or related documents Amendment Request and Assessment Form

○ State/describe the amendment :type of document/ part of document amended ○ Reasons for the amendment ○ 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)
Have the changes/ modifications in the amended versions been highlighted/ underlined? Yes No
Name of Principal Investigator: _____ Signature with Date:_____

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Type of review :- (Decision by the Chairperson/ Member Secretary)

Review by Member Secretary/ Chairperson || Review by
designated IEC members ||
Full Committee discussion and review ||

Comments of the reviewer :- _____

Decision:	Approved Suggested Recommendation(s) Disapproved Next full board discussion
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Name of IEC Member / Member Secretary / Chairperson reviewing the project:

Signature with Date:_____

Final Decision: Approved Yes No

If disapproved, reasons for
disapproval_____

Further revision or modification required:

Any Other

Signature of the Chairperson/Member Secretary:_____

Date:_____

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Annexure 3 AX 3/ SOP 09/VI

Proposal Amendment/Document Amendment Approval letter

To

..... (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 in the presence of following members:

- 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 IEC.

After reviewing, the IEC has decided to approve: (a) The aforementioned study-related documents OR (b) The following documents:

- 1.
- 2.

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

Yours truly,

Signature of IEC Chairperson/ Member Secretary with Date

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9.6. Flowchart

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