	<p><u>FERCI MODEL SOPs</u></p> <p><b><u>Review of Resubmitted and Amended Protocols and Protocol-related Documents.</u></b></p>	<p>SOP 09/V1:</p> <p><b><u>Effective Date: aa/bb/cccc</u></b></p>
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**Title: Review of Resubmitted and Amended Protocols and Protocol-related Documents**

**SOP Code: SOP 09/V1**

**Effective Date: aa/bb/cccc**

*[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]*

**Prepared by:**

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**Approved by:**

Dr. Vasantha Muthuswamy, FERCI President	(Signature with Date)
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## 1. Purpose

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

## 3. Responsibility

- It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC.
- A re-submitted protocol and related documents may be reviewed by either the Chairperson and 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 would be recorded (during the meeting) on the IEC Decision Form (*AX 03/SOP 7A/VI*).
- In the case of an amended study protocol and related documents, The 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/Chairperson can recommend an expedited review, while if the amendment/s relate to participant safety or data capture, it should be recommended for full

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board review. Additionally, primary reviewers who had reviewed the initial submission may be asked to review the resubmitted protocol.

#### **4. Detailed instructions**

##### **A] For resubmitted protocols**


##### ***4A1. 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.
- The Secretariat will check the resubmitted protocol & related documents (hard and soft copy) for the following items
  - 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 Secretariat will refer to the IEC Decision Form (*AX 03/SOP 7A/V1*) 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 designated IEC members if the decision on the protocol was ‘to be reviewed by two or more IEC members’.
  - 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.

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**4A2. 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 *AX 01/SOP 09/V1*.
- The Secretariat will retrieve the Assessment Form for resubmitted protocol *AX 01/SOP 09/V1* from the members/Member Secretary/Chairperson.
- 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 IEC members/Chairperson in the IEC Full Board meeting.
- The Chairperson shall entertain discussion on the protocol revision from all the IEC members.
- The final decision regarding the research project shall be reached by voting (2/3<sup>rd</sup> majority of the members present and voting) and shall include one of the following:
  - a) Approved
  - b) Modifications to items noted at the convened meeting and follow-up by the Chairperson/ Member Secretary /IEC members after receipt of the requested modifications:
  - c) Disapproved giving reasons for disapproval
- 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/V1.
- 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 Chairperson / Member Secretary will determine whether the protocol requires a full board review or expedited review. The Chairperson/Member Secretary will indicate this decision on the Protocol Amendment Assessment Form AX 02/SOP 09/V1.
- 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

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- 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 regulatory studies, a protocol amendment with above changes would require DCGI approval
  - For expedited review, Form AX 02/SOP 09/V1 will be used to nominate members by the Chairperson/ Member Secretary.

#### ***4B4. Distribution to IEC members***

- The following documents will be distributed to the designated IEC 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/V1*.
- 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 IEC member will review the amended documents and write his/her comments in the form - AX 02/SOP 09/V1.
- The reviewer may request the secretariat to keep the documents for full board discussion after review.

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- The IEC members performing the review must sign and date the form i.e. AX 02/SOP 09/V1 and return this to the Secretariat after the review.

#### ***4B6. IEC Decision on Amended Protocols***

- In case the project is kept for full board review, the 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 IEC review/ IEC 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 IEC decision will be recorded by the Secretariat in the IEC Decision Form.

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#### ***4B8. 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 i.e. AX 03/SOP 09/V1 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 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 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/V1 – Initial Full-Board Review of Research Study Protocols
- SOP 7B/V1 – Expedited Review of Research Study Protocols

#### **6. Annexures**

- Annexure 1      *AX 01/SOP 09/V1 - Assessment of resubmitted protocol*
- Annexure 2      *AX 02/SOP 09/V1 - Protocol amendment request and assessment form*
- Annexure 3      *AX 03/SOP 09/V1 - Protocol Amendment/Document Amendment Approval letter*


#### ***Annexure 1: AX 01/SOP 09/V1***



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***Assessment of Resubmitted Protocol***

Protocol Number	
Protocol Title:	
Number of review : <input type="checkbox"/> 2 <sup>nd</sup> Review <input type="checkbox"/> 3 <sup>rd</sup> Review <input type="checkbox"/> 4 <sup>th</sup> 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 _____)	
<b>Opinion of the reviewer:</b>	
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	_____ _____


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Name of the Reviewer: 1) _____	Signature: _____
Date: _____	
Name of the Reviewer: 2) _____	Signature: _____
Date: _____	
<b>Final Decision:</b> Approved    YES <input type="checkbox"/> NO <input type="checkbox"/>	
If disapproved, reasons for disapproval _____	
_____	
Further revision or modification required/ Resubmission <input type="checkbox"/>	
_____	
Any Other <input type="checkbox"/>	
Signature of the Member Secretary/ Chairperson: _____	
Date: _____	


***Annexure 2: AX 02/SOP 9/V1***

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

IEC Protocol Number: _____	
Protocol Title: _____	
_____	
Principal Investigator and Department: _____	
_____	
Approved date: _____	No. of amendment: _____

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<p>○ State/describe the amendment :type of document/ part of document amended</p> <hr/> <hr/>	
<p>○ Reasons for the amendment</p> <hr/> <hr/>	
<p>○ 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 )</p> <hr/> <hr/>	
<p>Have the changes modifications in the amended versions been highlighted/ underlined?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>Name of Principal Investigator: _____</p> <p>Signature with Date: _____</p>	
<p><b>Type of review :- (Decision by the Chairperson/ Member Secretary)</b></p> <p>Review by Member Secretary/ Chairperson <input type="checkbox"/></p> <p>Review by designated IEC members <input type="checkbox"/></p> <p>Full Board discussion and review <input type="checkbox"/></p>	
<p>Comments of the reviewer :- _____</p> <hr/>	
<p>Decision:</p>	<p><input type="checkbox"/> Approved <input type="checkbox"/> Suggested Recommendation(s)</p> <p><input type="checkbox"/> Disapproved <input type="checkbox"/> Next full board discussion</p>
<p>Name of IEC Member / Member Secretary / Chairperson reviewing the project:</p> <hr/>	
<p>Signature with Date: _____</p>	

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<b>Final Decision:</b> Approved      Yes <input type="checkbox"/> No <input type="checkbox"/>
If disapproved, reasons for disapproval _____
Further revision or modification required: <input type="checkbox"/>
Any Other _____
<b>Signature of the Chairperson/Member Secretary:</b> _____
Date: _____

***Annexure 3: AX 03/SOP 09/V1***

***Protocol Amendment/Document Amendment Approval letter***

To  
XXXXXX (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.

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

Yours truly,

\_\_\_\_\_  
Signature of IEC Chairperson/ Member Secretary with Date

## 7. 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