

Title: Review of Resubmitted Protocols

SOP Code: SOP/11/V1.1

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1. Purpose

This SOP describes how resubmitted study protocols are managed, re-reviewed and approved by the IEC.

2. Scope

This SOP applies to study protocols that have been reviewed earlier with recommendations from IEC for some corrections in the initial review process.

3. Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the IEC for reconsideration.

A re-submitted protocol may be reviewed and approved by either the Chairperson or some IEC members/reviewers, or full IEC. Decision for the review of the protocol should be determined by the IEC at the time of the initial review and mentioned in the minutes of the Ethics Committee meeting in which the proposal was discussed.

4. Flow chart

No.	Activity	Responsibility
1	Receive resubmitted protocol package ↓	Secretariat
2	Review the revised protocol ↓	Affiliated Members
3	Sending the protocol to external members/ reviewers ↓	Secretariat
3	IEC Meeting ↓	IEC Members
4	Communicate the IEC decision ↓	IEC Secretariat
5	Document the decision	IEC Secretariat

5. Detailed instructions

5.1 Receive protocol resubmitted package.

Check the received packages for:

Minutes of previous EC meeting

- Response to the comments by Investigators
Checklist (AF/EC/01/06/V1.3, see ANNEX 1 of SOP/06/V1.3)

- Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets, etc are included as part of the package.
- Changes made to the documents should be bold and the deleted matter should be made strikethrough for easy verification of the corrections done by the investigators.
- Put the stamp, write date and acknowledge the receipt of the protocol.

5.2 Review the revised protocol –Affiliated Members

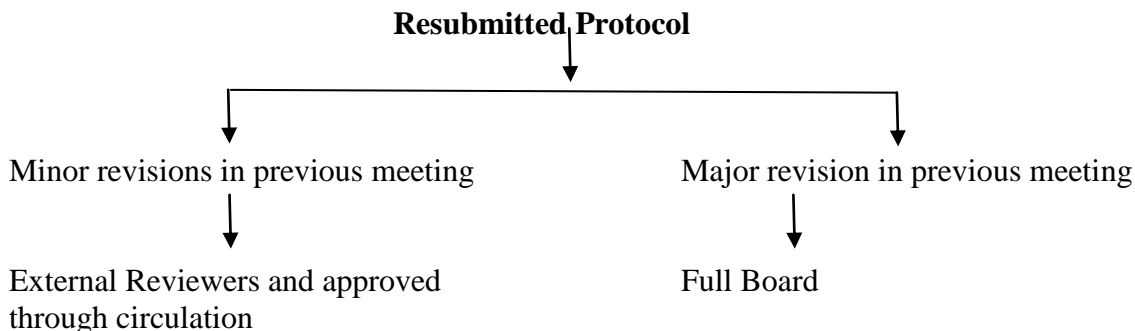
- Check the received protocol as per Checklist (AF/EC/01/06/V1.3)
- Refer to the meeting minutes as guidance for the review.
- Ensure that the response to comments of EC members as mentioned in the minutes is given by the investigator and page numbers where changes are made are mentioned in the proposal.
- Make further comments if the response is not satisfactory and the changes have not been incorporated in the study proposal.
- Internal reviewer's will write the comments on the Project Review Report form and will put signature with date.
- Notify the IEC Secretariat.
- Ask the Principal Investigator to make the necessary revisions.
- Send the resubmitted proposal with incorporated changes to reviewers /full board as per the decision in the minutes.
- If the proposal has only minor modifications as decided in the previous full board meeting, the proposal with incorporated changes is sent to external reviewers.
- The Secretariat to receive the package and inform the Member Secretary. Follow instructions in 5.4 respectively.

5.3 IEC meeting

If the IEC previously decided that major modifications to be made in the proposal , then the revision will be processed as :

- The primary reviewer presents a brief oral or written summary of the study design and his/her comments to the IEC members.
- The Chairperson entertains discussion on the protocol revision.
- Further recommendations for modifications to the protocol, consent form, as requested by the Committee are noted in the meeting minutes as 'with modifications made by IEC and will be communicated to the investigator.
- The Chairperson takes a consensus of the EC members on the revision to either:
 - Approve the study to start as presented with no modifications = *Approved*
 - Minor modifications for expedited review
 - Major modification for full board review
 - *Disapproved*

- *Flowchart for managing proposals with major and minor modifications*



5.4. Written Communication of the Decision

- The Secretariat then prepares the Approval letter and gets the member Secretary's and Chairperson's signature.
- If the study is approved, the Committee determines the frequency of Continuing Review for each study site (usually it should be once a year).
- The Secretariat sends an Approval letter to the investigator notifying the IEC decision and schedule of continuing review.
- The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- If the Committee requires modifications to any of the documents, the Secretariat sends a written request of the specific changes to the investigator to make the necessary changes and resubmit the documents to the IEC.

6. Glossary

Document All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or video tape.

7. References

- 7.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- 7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- 7.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

8. ANNEX

ANNEX 1 Document History AF/EC/01/11/V1.1

ANNEX 1

AF/EC/01/11/V1.1

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.1	24 th September 2014	<ul style="list-style-type: none"> • Correction in bullet 5.2 Review the revised protocol Included Minor modifications for expedited review Major modification for full board review and deleted the following * Approve the study to start with Committee approved modifications to the consent = <i>Approved with minor modification</i> * Require modifications to items noted at the convened meeting and follow -up by the Chairperson, after receipt of the requested modifications = <i>Approved with major modification</i>