4.1. Review of Resubmitted Protocols

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4.1. Review of Resubmitted Protocols

1. Purpose

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

2. Scope

This SOP applies to study protocols that have been reviewed earlier with major comments from IRB for corrections in the initial review process.

3. Responsibility

It is the responsibility of the IRB 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 IRB for reconsideration.

A re-submitted protocol may be reviewed and approved by either the Chairperson or some IRB members/reviewers, or full IRB. How the protocol will be reviewed should have been determined by the IRB at the time of the initial review. This information can be found on the Decision Section of the Assessment Form.

4. Flow chart

No.	Activity	Responsibility
1	Receive protocol resubmitted package	IRB Secretariat
	↓	
2	Review the revised protocol	IRB Members / Reviewers
	↓	
3	IRB Meeting	IRB Members / Reviewers
	↓	
4	Communicate the IRB decision	IRB Secretariat / Chairperson
	↓	
5	Document the decision	IRB Secretariat

5. Detailed instructions

5.1 Receive protocol resubmitted package

- Check the distributed packages for:
  - A written letter addressing the corrections with initials
  - Initial Review Application Form (EPHI-IRB AF 01-011/02.0)
  - 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
  - A separate letter indicating the changes made (addition or deletion) to the document with citation of the page, paragraph and statement lines on the document to describe where the changes or modifications made

Sign and date an acknowledgement form upon receiving the Reviewers

- packages
- Return the receipt form back to the delivery person IRB secretariat

5.2 Review the revised protocol

- Refer to the meeting minutes as guidance for the review
- Consider whether the recommendation of the IRB has been followed
- Make further comments where appropriate
- Covering letter dated and signed by the Secretariat annexed with the reviewer's comment
- Notify the IRB Secretariat

5.3 IRB meeting

- The Secretariat receives the review report and informs the Chairperson.
- If no IRB meeting is necessary, then go to step 5.4
- If the IRB previously decided to see the new revision, then proceed with the following steps:
  - The primary reviewer presents a brief oral or written summary of the study design and his/her comments to the IRB members
  - The Chairperson entertains discussion on the protocol revision.
  - Further recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the board are noted in the meeting minutes as 'with modifications made by IRB' and will be communicated to the investigator.
  - The Chairperson calls for a vote on the revision to either:

- Approve the study to start as presented with no modifications = *Approved*
- Approve the study to start with board approved modifications to the consent = *Approved with minor modification*
- Require modifications to items noted at the convened meeting and follow-up by the Chairperson, after receipt of the requested modifications = *Approved with major modification*
- *Disapproved*

5.4 Document the IRB decision

- Place the original completed documents along with the completed re-review report, the Assessment Form and the Initial Review Application Form as well as the others in the protocol package.
- Prepare an approval letter.
- Get the Chairperson's signature.
- Send an approval letter to the principal investigator.

5.5 Communicate the decision

- The secretariat notifies the principal investigator about the decision of the IRB through e-mail communication and files the "sent" and "received" e-mail messages in the protocol file.
- The Secretariat then prepares the Approval/Action Letter and gets the Chairperson's signature.
- If the study is approved, the board determines the frequency of Continuing Review for each study site.
  - The Secretariat sends an Action Letter to the investigator notifying the IRB's decision and schedule of continuing review.
  - The letter contains, at a minimum, a listing of each document approved, the date set by the board for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
  - A computer-generated approval and expiration date are placed on every page of each consent form approved by the IRB.
- If the board requires modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator to make the necessary changes and resubmit the documents to the IRB.

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6. Glossary

Completed assessment form	An official record of the review decision along with comments and dated signature of the reviewer.
Document	All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or video tape.

7. References

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.
3. Associated SOPs: EPHI-IRB SOP/010/02.0

8. Annex

Annex1: Resubmitted Protocol Review Form
(EPHI-IRB AF 01-013/02.0)

Protocol No.:		EPHI-IRB-☐☐☐-☐☐☐☐
Protocol Title:		
Total Participants :		☐ 2nd Review ☐ 3rd Review ☐ 4th Review
Principal Investigator:		Tel.:
Initial Review Date:		Last Review Date:
IRB Decision recorded in the meeting minute:	☐ Approved ☐ Minor changes or recommendation ☐ Major changes or recommendation for resubmission ☐ Disapproved	
Opinion of the reviewer: • Revision or Modification according to the recommendation • What need to be further revised:	☐ Yes ☐ No: Explain:…….. …….. …… …… …… ……	

SIGNATURES:

_____ Date:…….
Protocol Reviewer

APPROVAL:

_____ Date: ……..
Chairperson, EPHI-IRB

COMPLETION:

_____ Date:…….
Secretary, EPHI-IRB