CHAPTER 4.1

REVIEW OF RESUBMITTED PROTOCOLS

SOP NUMBER: SOP/013/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

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Author: SOP Team — Date: September 29, 2021
Approved by: Chairperson, IRB — Date: September 30, 2021
Name: ***Dr. Karma Tenzin***

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1. PURPOSE

This procedure describes how resubmitted study protocols shall be managed, re-reviewed and approved by the IRB.

2. SCOPE

This SOP shall apply to study protocols that have been reviewed earlier with recommendations from IRB for some corrections in the initial review process requested to be resubmitted for review.

3. RESPONSIBILITY

The IRB Secretariat shall be responsible 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 Board. How the protocol shall be reviewed should have been determined by the IRB at the time of the initial review. This information can be found on the Decision Form (AF 04-012/01).

4. FLOW CHART

No.	Activity	Responsibility
1	Receive protocol resubmitted package and distribute to the primary reviewers ↓	IRB Member Secretary
2	Review the revised protocol ↓	Primary Reviewers
3	Include in the IRB meeting agenda ↓	IRB Member Secretary
4	IRB Meeting ↓	IRB Members / Reviewers
5	Communicate the IRB decision to the investigator ↓	IRB Secretariat / Chairperson
6	Storage of the documents	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Receive protocol resubmitted package and distribute to the reviewers.

5.1.1. Check the submitted packages and complete the submission process (refers to SOP/008/01 – Management of Protocol Submission, section 5.3). The package includes:

5.1.1.1. Memorandum addressing the corrections,

5.1.1.2. 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.

5.1.1.3. Changes made to the documents should be underlined or highlighted.

5.1.2. Distribute the protocol package to the reviewers.

5.1.2.1. Referring to the information on the decision form of the previous meeting whether the resubmitted protocol is for expedited or full board review.

5.1.2.1.1. If for Expedited Review, refer to SOP 009 – Expedited Review

5.1.2.1.2. If for full board review, distribute the package to the previous primary reviewers.

5.1.2.2. The protocol package includes the submitted documents listed in 5.1.1, along with previous review meeting minutes, the decision form of the previous meeting, Resubmitted Protocol Review Form (AF/01-013/01), and the due date for the review.

5.2. Review the revised protocol.

5.2.1. Refer to the meeting minutes and/or the action letter as guidance for the review.

5.2.2. Consider whether the recommendation of the IRB has been followed.

5.2.3. Complete the Resubmitted Protocol Review Form (AF/01-013/01).

5.2.4. Notify the IRB Secretariat by the due date.

5.3. IRB meeting

5.3.1. The Secretariat receives the review report and informs the Chairperson.

5.3.2. If no IRB meeting is necessary, then go to step 5.4.

5.3.3. If the IRB previously decided to see the new revision, then proceed with the following steps:

5.3.3.1. The primary reviewer shall present a brief oral or written summary of the study design and his/her comments to the IRB members.

5.3.3.2. The Chairperson shall entertain discussion on the protocol revision.

5.3.3.3. 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 shall be communicated to the investigator.

5.3.3.4. The Chairperson shall call for a vote on the revision to either:

5.3.3.4.1. Approve the study to start as presented with no modifications (**Approved**)

5.3.3.4.2. Approve the study to start with Board approved modifications to the consent (**Approved with minor modification**)

5.3.3.4.3. 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)**

5.3.3.4.4. **Not Approved**.

5.3.3.5. The IRB Member Secretary shall record the Board's decision on the Decision Form and the Chairperson shall sign for the approval.

5.4 Communicate the IRB decision to the investigator (Refer to SOP/010/01 – Initial Review, section 5.6)

5.5 Storage of the documents (Refer to SOP/010/01– Initial Review, section 5.7)

6. GLOSSARY

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

7. REFERENCES

7.1. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.
7.2. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
7.3. World Health Organisation, Standards and operational guidance for ethics review of health-related research with human participants, 2011
7.4. Associated SOPs: SOP/010/01.

8. ANNEX

ANNEX 1 AF/01-013/01 Re-submitted Protocol Review Form
ANNEX 2 AF/02-013/01 Application Form for Resubmitted Protocol Review

ANNEX 1
AF 01-013/01

Resubmitted Protocol Review Form

Protocol No.:	Version No.: dated DD/MM/YYYY
Protocol Title:	
Principal Investigator:	
Proponent of the study:	
☐ 2nd Review ☐ 3rd Review ☐ 4th Review ☐ ...th Review *(**NB**: Consider Initial review to be the 1st review)*	
Initial Review Date:	Last Review Date:
Previous Decision of IRB: ☐ Approved with Recommendations ☐ Resubmission ☐ Disapproved	
✧ Recommendations/clarifications sought in previous review	
1.	☐ Addressed ☐ Not Addressed
2.	☐ Addressed ☐ Not Addressed
3.	☐ Addressed ☐ Not Addressed
4.	☐ Addressed ☐ Not Addressed
✧ Other revisions, is any:	
1.	
2.	
✧ What need to be further revised, if required:	

Decision of the reviewer ☐ Approve ☐ Approve with Recommendations ☐ Solicit for Resubmission ☐ Disapprove

If approved, frequencies for continuing review (CR): ... *(**NB**: Default schedule for CR is one month before the approval expiry date)*

SIGNATURES:

_____ Date: ……

Protocol Reviewer

ANNEX 2
Form AF/02-013/01

APPLICATION FORM for RESUBMITTED PROTOCOL REVIEW

1. Protocol Number (*To be assigned by IRB Secretariat*): ...

2. Protocol Title: ...

2.1. Protocol Version No.: ... Dated: ...

3. PARTICULARS OF THE PRINCIPAL INVESTIGATOR (PI)

Name: ……

Address: ……

Telephone: …… Fax(optional): ……..

E-mail: …….....

3.1 Proponent of the study: …….....

4.	Recommendations/clarifications sought in previous review:	Clarification/Action Taken
	1.	
	2.	
	3.	
	4.	
	5.	
	6.	
	7.	
	8.	

5.	Other revisions, is any:
	1.
	2.
	3.
	4.

SIGNATURES:

_____ Date: ……..

Principal Investigator

_____ Date:……

Protocol Chairperson (if applicable)

COMPLETION:

_____ Date: ……

Member Secretary, IRB