CHAPTER 4.4

REVIEW OF FINAL REPORT

SOP NUMBER: SOP/016/01

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

The purpose of this SOP shall be to provide instructions on the review and follow-up, if appropriate, of Final Reports for any study previously approved by IRB.

2. SCOPE

This SOP shall apply to the review and follow-up of the Final Report which is an obligatory review of each investigator's activities presented as a written report of studies completed to the IRB.

Although IRB provides a Study Report Form, ANNEX - AF/01-016/01 to the investigator, any mechanism (letter format, form provided by the Sponsor, etc.) may be used, provided that the information submitted is sufficient.

3. RESPONSIBILITY

The IRB secretariat shall be responsible to review the report for completeness before sharing with the Primary Reviewers and Chairperson. The IRB shall be responsible to review the final report and decide whether any further information or follow-up is required.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive final report ↓	IRB Secretariat
2	Send to Primary reviewers for comments/approval ↓	IRB Member Secretary
3	Include in the agenda for next meeting ↓	IRB Member Secretary
4	Activities during meeting ↓	IRB Secretariat / Members / Chairperson
5	Activities after the board meeting	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Receive Final report

5.1.1. See SOP/008/01 (Management of Protocol Submission) for receiving and checking the report packages.

5.1.2. The IRB Member Secretary shall review the submitted report for completeness and brief the Chairperson.

5.2. Sends to Primary reviewers

5.2.1. IRB Member Secretary shall send the report to the primary reviewers for comments and approval

5.2.2. Primary reviewer(s) shall review the report using Format for Review of Research Report, ANNEX - AF/02-016/01, and approves or provides comments on the report

5.2.3. If primary reviewers consent to same decision then the IRB Member Secretary shall prepare the review/approval letter and send it to the Chairperson along with the copies of the review forms for endorsement.

5.2.4. If there is no consensus in the decision between the primary reviewers then the Chairperson may either take the final call or forward the report to full board.

5.3. During the meeting

5.3.1. The primary reviewers shall present the reports to the Board member

5.3.2. The Chairman shall entertain any discussion of the study.

5.3.3. If appropriate to the discussions, an IRB member may call for consensus on whether to request further information or to take other action with the investigator.

5.3.4. Summarize what action shall be taken.

5.4. After the meeting

5.4.1. Note the decision in the meeting minutes

5.4.2. Communicate the decision to the investigator

5.4.3. If no further action from the IRB,

5.4.3.1. Send an acknowledged letter to the investigator.

5.4.3.2. Get a copy of the final report signed by the Chairperson.

5.4.4. If any follow-up actions required by the Board,

5.4.4.1. Send a letter with the signature of the Chairperson to the investigator informing the Board's decision within five working days of the meeting.

5.4.5. Refer to SOP 025 – Achieves and Retrieval of the Documents, Section 5.1 "After Receiving the Final Report", if the study is considered closed.

6. ANNEX

ANNEX 1	AF/01-016/01	Study Report Form
ANNEX 2	AF/02-016/01	Format for Review of Research Report
ANNEX 3	AF/03-016/01	Report Review Letter Template

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) 2016.

7.3. World Health Organization, Standards and operational guidance for ethics review of health-related research with human participants Guidance document, 2011

7.4. Related SOP/008/01

ANNEX 1
AF/01-016/01

Study Report Form

Protocol No.:		**Protocol Title :**
Principal Investigator:		
Phone number:		E-mail address :
Sponsor's Name		
Address:		
Phone :		E-mail :
Study site(s):		
Total Number of study participants :		No. of Study Arms:
Number of participants who received the test articles:		
Study materials:		
Treatment form:		
Study dose(s): (if applicable).		
Duration of the study		
Objectives:		
Results: (Use extra blank paper, if more space is required.)		
Signature of P.I.:		Date:

ANNEX 2
AF/02-016/01

Format for Review of Research Report

I. Protocol No:					
Protocol Title:					
Principal Investigator:					
II. Elements of Review					
Sl No.	**Protocol parameters**	**Reviewer's observation** *(Please mark 'X' in relevant cages)*			
		Same as approved by IRB	**Minor diversion from that IRB by approved**	**Major diversion from that approved by IRB**	**Remarks**
1	Protocol Title				
2	Type of study				
3	Principal investigator(s)				
4	Co-investigator(s)				
5	Objectives				
6	Sample size				
7	Sampling method				
8	Inclusion criteria				
9	Exclusion criteria				
10	Recruitment of subjects				
11	Discontinuation & withdrawal criteria				
12	Voluntary, non-coercive recruitment of subjects				
13	Involvement of vulnerable subjects				
14	Informed consent procedures				
15	Data collection tools				
16	Data analysis				
17	Privacy & Confidentiality				
18	Risk-Benefit assessment / management				
Any other comments:					

IV. Reviewer's Recommendation on Closure of Research project

I certify that I have made the foregoing observations on the basis of my objective assessment of the protocol and the final report and I confirm that I have complied with the IRB policies and guidelines in reviewing this report.

I, therefore, recommend that the report shall be;

- ☐ Approved and the protocol file shall be closed as the PI has adhered with the approved protocol and the report is technically sound.
- ☐ Approved and the protocol file shall be closed; however, the PI shall be reprimand for minor violation(s) (specify violations/comments).....
- ☐ Either resubmitted with revision or justifications shall be provided for the major violations (specify the violations/comments).....

Signature of Reviewer: …….

Name of Reviewer: ……

III. IRB Endorsement

The recommendation of the reviewer of research report is endorsed/approved by:

A. By Board Members

1. Unanimous decision ☐
2. By Voting : ☐

i. For: …….....
ii. Against: …….....
iii. Total voting members: ……

B. By Chairperson

1. Approved: ☐
2. Not approved: ☐

Signature: ……
Office seal:

ANNEX 3
AF/03-016/01 REPORT REVIEW LETTER TEMPLATE

གེ་སར་རྒྱལ་པོ་གསོ་རིག་གཙུག་ལག་སློབ་སྡེ།།

Khesar Gyalpo University of Medical Sciences of Bhutan
Royal Government of Bhutan

Ref. No. IRB/PN/2021/008 Date:

REPORT REVIEW LETTER

The

……..

……..

Subject: Closing letter for PN/2021/008 "**……..**"

Dear Doctor,

The Report of protocol No PO/2021/008 titled "**……..**"submitted to IRB was reviewed by the IRB and the report is;

☐ Approved and the protocol file is closed.

☐ Approved and the protocol file is closed; however, the PI is reprimanded for the following minor violation(s) (specify violations/comments)……

……

☐ Called for resubmission with revision or justifications for the following major violations shall be provided for review by IRB (specify the violations/comments)……..

Congratulation for the successful completion of the study! And thank you for complying with the conditions of approval.

Or

Specify violations/comments:
1
2
3

Yours sincerely

( )

Chairperson

For further information please contact: *…@kgumsb.edu.bt; Member Secretary*