CHAPTER 1.1

WRITING, REVIEWING, DISTRIBUTING AND AMENDING STANDARD OPERATING PROCEDURES (SOP) FOR ETHICS BOARD

SOP NUMBER: SOP/001/01

INSTITUTIONAL REVIEW BOARD (IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

Effective Date: October 01, 2021
Supersedes: SOP/001/yy

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 Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the Institutional Review Board (IRB). The SOPs shall provide clear and unambiguous instructions so that the related activities in the Ethics Board are conducted in accordance with the WHO Operating Guidelines for Ethical Review Committee that reviews Biomedical Research, *National Guideline for Ethics Committees*, ICH (International Conferences on Harmonization) and Good Clinical Practice (GCP).

2. SCOPE

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the IRB.

3. RESPONSIBILITY

The secretariat of IRB shall be responsible for appointment of the SOP Team to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the IRB.

3.1. Secretariat of IRB shall:

3.1.1. Co-ordinate activities of writing, reviewing, distributing and amending SOPs
3.1.2. Maintain in file all current SOPs and the list of SOPs
3.1.3. Maintain an up-to-date distribution list for each SOP distributed
3.1.4. Distribute the SOPs with a receipt to all users
3.1.5. Ensure all IRB members and Administrative staff involved have access to the SOPs
3.1.6. Ensure that all IRB members and involved staff are working according to current version of SOPs
3.1.7. Review the SOPs at least every *two years* and record the dates of review on the SOP Master file

3.2. SOP team shall:

3.2.1. Propose required SOPs
3.2.2. Select the format and coding system
3.2.3. Draft the SOP in consultation with IRB members and involved administrative staff
3.2.4. Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson

3.3. IRB members and involved administrative staff shall:

3.3.1. Propose revision of the SOP
3.3.2. Draft, discuss and review new SOP
3.3.3. Sign and date when they receive the approved SOPs
3.3.4. Maintain a file of all SOPs received
3.3.5. Return all out-of-date SOPs to the Secretariat

3.4. Chairperson of the IRB shall:

3.4.1. Approve the reviewed SOPs
3.4.2. Sign the approved SOPs and specifies the effective dates

4. FLOW CHART

No.	Activity	Responsibility
1	Appoint the SOP Team ↓	Secretariat
2	List all relevant SOPs ↓	SOP Team
3	Design a format and layout ↓	SOP Team
4	Draft a new/revise SOP ↓	SOP Team
5	Discuss the new/revise SOP ↓	IRB members Relevant administrative staff
6	Approve the new/revise SOP ↓	Chairperson
7	Implement, distribute and file all SOPs ↓	Secretariat
8	Review and request for a revision of existing SOPs ↓	SOP Team / IRB members/ administrative staff/chairperson
9	Manage and archive superseded SOPs	Administrative staff

5. DETAILED INSTRUCTIONS

5.1. Appoint the SOP Team

5.1.1. The secretariat shall appoint the appropriate IRB members who have a thorough understanding of ethical review process to form the SOP writing team.

5.2. List all relevant SOPs

5.2.1. Write down step by step all IRB procedures.

5.2.2. Organize, divide and name each process.

5.2.3. Make a list of SOPs with coding reference (*AF/01-001/01)*

5.3. Format and layout

5.3.1. Each SOP shall be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format SOP/XXX/YY shall be assigned to each SOP item by the *Secretariat.* XXX is a three-digit number assigned specifically to the SOP. YY is a two-digit number identifying the version of the SOP, The number of version shall start from 01.

5.3.2. Each annex shall be given unique code number with the format *AF/BB-XXX/YY*. AF is the abbreviation for Annex Form. BB is a two-digit number identifying the number of the annex, for example AF/01-001/01 means Annex Form number one of the *SOP/001/01.*

5.3.3. Each SOP shall be prepared according to the standard template. Please refer to Annex 2 – *AF/02-001/01*.

5.4. Draft a new/revised SOP

5.4.1. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form (Annex 3 – *AF/03-001/01*).

5.4.2. When the need for a new SOP has been identified and agreed on, a draft shall be written by a designated member of the SOP team.

5.5. Discuss the new/revised SOP

5.5.1. The draft SOP shall be discussed with IRB members and all relevant administrative staff. The SOP shall be agreed upon by the people involved in that particular task.

5.6. Approve the new/revised SOP

5.6.1. The final version shall be passed to the Chairperson for review and approval. The Chair shall decide the effective date of the new SOP.

5.7. Implement, distribute and file all SOPs

5.7.1. The approved SOPs shall be implemented from the effective date.

5.7.2. The approved SOPs shall be distributed to the IRB members and the relevant staff by the Secretariat according to the distribution list. (Annex 4 – *AF/04-001/01*). When revised version is distributed, the old version shall be retrieved and destroyed.

5.7.3. One complete original set of current SOPs shall be filed centrally in the SOP Master file by the Secretariat. The Master file shall be kept in the office of the IRB.

5.8. Review and request for a revision of an existing SOP

5.8.1. Any member of the IRB or Secretariat who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure shall use the form in Annex 5 – *AF/05-001/01* to make a request.

5.8.2. If the Board agrees with the request, an appropriate team shall be designated to proceed with the revision process. If the Board does not agree, the chairperson shall inform the person who made the request of the decision.

5.8.3. Revision of the SOPs shall be reviewed and approved in the same manner as new SOPs (section 5.4-5.6)

5.8.4. The Secretariat is expected to review the SOPs at least every two years and record the dates of review in the SOP Master file.

5.9. Manage and archive superseded SOPs

5.9.1. One copy of the superseded SOPs shall be retained and clearly marked "superseded" and archived in the historical file by the Secretariat.

6. GLOSSARY

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describe all activities and action undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.
IRB members	Individuals serving as regular member of the IRB.
SOP Team	A selected team from the IRB members and other staff who will oversee the creation, preparation, review and periodic revision of the institute SOPs.
Master SOP files	An official collection of the institute Standard Operating Procedures (SOP) accessible to all staff, IRB members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all pre-planned deviations.

7. REFERENCES

1.1. WHO. Standards and operational guidance for ethics review of health-related research with human participants (2011). (http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf - accessed 28 October 2017)

1.2. ICH Harmonised Guideline. Integrated Addendum To ICH E6(R1): Guideline For Good Clinical Practice E6(R2) Current Step 4 version dated 9 November 2016 (https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf - accessed 28 October 2017)

8. ANNEX

ANNEX 1	AF 01-001/01	List of IRB SOPs
ANNEX 2	AF 02-001/01	Standard Operating Procedures Template
ANNEX 3	AF 03-001/01	Document History
ANNEX 4	AF 04-001/01	Log of SOP Recipients
ANNEX 5	AF 05-001/01	Request for Revision of an SOP

ANNEX 1
AF 01-001/01

List of IRB SOPs

Topic No.	Topics/ Standard Operating Procedures (SOPs)	Chapter/ SOP Code
	Glossary and Definition of Terms	
	Table of Contents	
1.	Preparing Standard Operating Procedures (SOPs) and Guidelines for Ethics Boards/ IRBs	Chapter 1
1.1.	Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Boards/ IRBs	SOP/001/01
1.2.	Preparation of Guidelines	SOP/002/01
2	Constituting an Ethics Board/ Institutional Review Board (IRB)	Chapter 2
2.1.	Constituting an IRB	SOP/003/01
2.2.	Confidentiality /Conflict of Interest Agreements	SOP/004/01
2.3.	Training Personnel and IRB Members	SOP/005/01
2.4.	Selection of Independent Consultants	SOP/006/01
3.	Initial Review Procedures	Chapter 3
3.1.	Determination of Research Qualifying from Exemption of Ethics Review	SOP/007/01
3.2.	Management of Protocol Submissions	SOP/008/01
3.3.	Expedited Reviews	SOP/009/01
3.4.	Initial Review of Research/ Application Protocols	SOP/010/01
3.5.	Review of New Medical Devices Studies	SOP/011/01
3.6.	Use of Study Assessment Form	SOP/012/01
4	Protocol Amendments, Continuing Review, and End of Study	Chapter 4
4.1.	Review of Resubmitted Protocols	SOP/013/01
4.2.	Review of Protocol Amendments	SOP/014/01
4.3.	Management of Protocol Continuing Reviews	SOP/015/01
4.4.	Review of Final Reports	SOP/016/01
5	Monitoring Protocol Implementation	Chapter 5
5.1.	Intervention in Protocol Deviation/Non-Compliance/Violation	SOP/017/01
5.2.	Response to Research Participants' Request	SOP/018/01
5.3.	Management of Study Termination	SOP/019/01
6	Monitoring and Evaluation of Adverse Events	Chapter 6
6.1.	Review of Serious Adverse Events (SAE) Reports	SOP/020/01
7	Site Monitoring	Chapter 7
7.1.	Site Monitoring Visits	SOP/021/01
8	Preparation of Review Meeting Agenda and Communication Records	Chapter 8
8.1.	Agenda Preparation, Meeting Procedures and Minutes	SOP/022/01
8.2.	Emergency Meeting	SOP/023/01
8.3.	Communication Records	SOP/024/01
9	Managing Study Files	Chapter 9
9.1.	Maintenance of Active Study Files	SOP/025/01
9.2.	Archives and Retrieval of Documents	SOP/026/01
9.3.	Maintaining Confidentiality of IRB's Documents	SOP/027/01
10	Evaluating an IEC/IRB	Chapter 10
10.1	Audit and Inspection of the IRB	SOP/028/01

ANNEX 2
AF 02-001/01

Standard Operating Procedures Template

Name of Institution			
Title:	*Title which is self-explanatory and is easily understood*		
SOP No:	*SOP/xxx/yy*	Page:	of

TITLE *Title which is self-explanatory and is easily understood*

Effective Date: Supersedes:	
Author: *(Name).*	Date:
Approved by: *(Name)*	Date:

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Main Text:

Purpose - *summarizes and explains the objectives of the procedure.*

Scope – *states the range of activities that the SOP applies to.*

Responsibility – *refers to person(s) assigned to perform the activities involved in the SOP*

Flow chart – *simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*

Detailed instructions – *describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.*

Glossary – *clarifies uncommon or ambiguous words or phases by explanation.*

Reference – *lists sources of the information given in the SOP.*

ANNEX - documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.

ANNEX 3
(AF/03-001/01)

Document History

(The first draft 00 of the SOP History **shall** be produced as the output of the first circulation of the document and the final version is the version after the approval by the Chairperson which is 01)

Author	Version	Date	Amendment Number
SOP Team	00	*29-09-20*	First Draft
Dr. Karma Tenzin	01	*30-09-20*	Final Version
SOP Team	02	*dd-mm-yy*	Amendment 01
SOP Team	03	*dd-mm-yy*	Amendment 02
SOP Team	04	*dd-mm-yy*	Amendment 03
SOP Team	05	*dd-mm-yy*	Amendment 04
SOP Team	06	*dd-mm-yy*	Amendment 05
SOP Team	07	*dd-mm-yy*	Amendment 06

** For routine review without change, the SOP number and version shall remain same. However, the review date shall be minuted and documented in the SOP/001/01.

Summary of the Changes made in the SOP

A. Amendment 01, Month dd, yyyy

1. Chapter 1.1 SOP/001/01: Record what changes/amendments made ……
2. ……
3. ……
4. ……
5. ……
6. ……
7. ……

B. Amendment 02, Month dd, yyyy

1. Chapter 1.1 SOP/001/02: Record what changes/amendments made …….
2. ……..
3. ……..
4. ……..
5. ……..
6. ……..
7. ……..

C. Amendment 03, Month dd, yyyy

1. Chapter 1.3 SOP/001/03: Record what changes/amendments made …….
2. ……..
3. ……..
4. ……..
5. ……..
6. ……..
7. ……..

D. Amendment 04, Month dd, yyyy

1. Chapter 1.4 SOP/001/04: Record what changes/amendments made …….
2. ……..
3. ……..
4. ……..
5. ……..
6. ……..
7. ……..

ANNEX 4
(AF/04-001/01)

Log of SOP Recipients

No.	Name of Recipients	No. of Copies	Signature	Date
1	*Chairperson*			
2	*Dr. XXXX*			
3	Drg. YYYY			

ANNEX 5
AF/05-001/01

Request for Revision of an SOP

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP/ / (Write the SOP number)	
Title:	
Details of problems or deficiency in the SOP:	
Identified by:	Date (D/M/Y): Click here to enter a date.
Discussed with:	
SOP revision required: ☐ Yes ☐ No	
If yes, to be carried out by whom?	
If no, why not?	
Date SOP re-finalized:	Click here to enter a date.
Date SOP approved:	Click here to enter a date.
Date SOP becomes effective:	Click here to enter a date.