CHAPTER 1.2

PREPARATION OF GUIDELINES

SOP NUMBER: SOP/002/01

Institutional Review Board
[IRB]

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

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Approved by: Chairperson, IRB *Name:* ***Dr. Karma Tenzin***	Date: September 30, 2021

Table of Contents

1. PURPOSE

This procedure describes how to prepare a new guideline or update an existing one. It will also guide in developing the layout and format of each guideline.

2. SCOPE

This SOP applies to IRB guidelines and their amendment versions published and distributed by the IRB.

The IRB works according to internal rules that shall be described in the written SOPs. The SOPs are publicly available. In order to maintain a transparent relationship with non-members of the IRB, certain procedures shall form guidelines for use by investigators, scientific experts and by the Institute personnel.

3. RESPONSIBILITY

The IRB Secretariat or designated IRB members shall be responsible for the preparation or amendment of the guidelines as and when the need arises. The designated IRB members shall manage the preparation/amendment of the guidelines with the assistance of the Secretariat.

4. FLOW CHART

No.	Activity	Responsibility
1	Numbering of Guidelines ↓	IRB Secretariat
2	Numbering of the Version ↓	IRB Secretariat
3	Contents and Layout of A Guideline ↓	IRB Secretariat
4	Approval of New and Updated Guidelines ↓	IRB Chairperson
5	Information for Personnel ↓	IRB Members / Secretariat
6	Distribution of Guidelines	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Numbering of the Guidelines

5.1.1. SOP/001/01 lists all procedures used by the IRB in relation to preparing of guidelines.

5.1.2. When a new guideline is created, a subsequent number shall be allocated at the end of the list of existing guideline.

5.1.3. When a guideline is no longer used, its status is changed to “inactive”. It is not allowed to reuse the guideline number of an inactive guideline.

5.1.4. All guidelines are named and numbered in the following way :

GL 01 to GL 99

5.2. Numbering of the Version

5.2.1. Number guideline versions as follows:

5.2.1.1. Draft versions:

All draft versions are always indicated as “version 01" followed by the word “draft”.
For example: Version 01, draft

5.2.1.2. For any changes on a final version:
Version V, final to Version (V+1), final
For example, any changes on “version 01, final” shall be indicated as “version 02 final”.

5.3. Contents and Layout of a Guideline

1. Cover Page
2. A new or updated guideline has five sections:
3. Table of Contents
4. Main text
5. References
6. Appendices

Sections 1 to 4 are mandatory. The *“Appendices”* section is not mandatory.

5.3.1. Cover Page

The cover page shall have the following information:

5.3.1.1. Logo of the IRB/KGUMSB and related information (address, telephone number, fax number, email address).
5.3.1.2. Title and number of the guideline, date of implementation of the guideline
5.3.1.3. Date of the previous issues. If not applicable, the date of pervious issue is indicated by “N/A” (= not applicable).
5.3.1.4. Name (directory names and path included) of the corresponding computer document, if relevant.
5.3.1.5. Name of the editors and address of the contact office.
5.3.1.6. A copyright declaration.
5.3.1.7. Refer to *ANNEX 1 (AF/01-002/01)* for an example of a cover page.

5.3.2. Table of Contents

The table of contents lists all major headers and subheadings of the guideline, including the appendices and page numbers on which these appear in the guideline.

5.3.3. Main Text

5.3.3.1. Introduction

5.3.3.1.1. Summarize and explain the purpose of the guideline.
5.3.3.1.2. A short note on how the guideline was prepared.
5.3.3.1.3. A short note on how to use the guideline.

5.3.3.2. Detailed description

5.3.3.2.1. The final text shall be short and clear.
5.3.3.2.2. Long guidelines shall be split into shorter ones.
5.3.3.2.3. Wherever possible and relevant references shall be added
5.3.3.2.4. Limitation of the guidelines may be mentioned

5.3.4. Appendices

5.3.4.1.1. Replace long and complex descriptions.
5.3.4.1.2. “Descriptions-by-example” are always recommended to avoid writing difficult and hard to understand texts.
5.3.4.1.3. Glossary
5.3.4.1.4. Full form of abbreviations

5.4. Approval of New and Updated Guidelines

5.4.1. The members of the IRB shall prepare a new guideline or update an existing guideline.
5.4.2. The Chairperson of the IRB and the President of KGUMSB shall approve each new or updated guideline.
5.4.3. The final version is the one to be implemented.

5.5. Information for Personnel

5.5.1. All members of the IRB shall read and understand a new or updated guideline.
5.5.2. Each member shall sign a form indicating that they have read and understood each new or updated guideline.
5.5.3. Refer to *ANNEX 2 (AF/02-002/01)* for an example.
5.5.4. If the guideline is for investigators/students/institute personnel then they shall be given a copy of the guideline after taking their signature.

5.6. Distribution of Guidelines

5.6.1. Guidelines are not confidential and may be disclosed for use by investigators, scientific experts and IRB members.
5.6.1.1. A Log of Guideline Distribution shall be maintained for inventory records *ANNEX 3 (AF/03-002/01)*.

6. GLOSSARY

Guideline	Any suggestion, rules, etc., intended as a guide for specific practice
Head of the organization	President of KGUMSB, Thimphu, Bhutan

7. REFERENCE

7.1. 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)
7.2. 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/01-002/01	Cover page of a Guideline (2 pages)
ANNEX 2	AF/02-002/01	Lists of Signatures
ANNEX 3	AF/03-002/01	Log of Guideline Distribution

ANNEX 1
AF/01-002/01

Cover page of a Guideline

Guideline for

…… ……

Version No……

Institutional Review Board

Address:

ANNEX 1
Form AF/01-002/01

Information on the Back of the Cover Page

Number of Copies Printed

Title of the Guideline

Version No.

Month/Year of Publication

ISBN:

Author:

Editor:

Publisher:

Computer Record

ANNEX 2
AF/02-002/01

LIST OF SIGNATURES

Title of the Guideline: ……..

Number of the Guideline: GL …….

The following listed persons with their signatures have read this guideline.

No.	Full Name of IRB members	Signature	Date

ANNEX 3
AF/03-002/01

Log of Guideline Distribution

#	Name of Recipients	Affiliation	Guideline#	No. of Copies	Date