Table of Contents

1.2. Preparation of Guidelines

1. Purpose

This SOP describes how to prepare a new guideline or update an existing one as well as the layout and format of each guideline.

2. Scope

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

The Institutional Review Board (IRB) of the Ethiopian Public Health Institute (EPHI) works according to internal rules that must be described in written standard operating procedures (SOPs). The approved SOP will be uploaded in the EPHI Webpage.

3. Responsibility

It is the responsibility of the IRB and/or Secretariat and/or designated persons to prepare or amend the Institute guidelines as and when the need arises. The designated persons will 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 and/or Secretariat
	↓	
4	Drafting of Guideline	IRB and/or Secretariat and/or designated persons
	↓	
5	Approval of New and Updated Guidelines	IRB Chairperson
	↓	
6	Endorsement of approved guideline	Director General
	↓	
7	Information for Personnel	IRB Secretariat
	↓	
8	Distribution of Guidelines	IRB Secretariat

5. Detailed instructions

5.1. Numbering of the Guidelines

- Procedure EPHI-IRB SOP/002/2.0 lists all procedures and guidelines used by the IRB of the institute
- When a new guideline will be created, a subsequent number should be allocated at the end of the list of existing Guidelines
- 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
- All guidelines are named and numbered in the following way: GL# EPHI-IRB 01/XX.W to GL#EPHI-IRB 99/XX.W (XX Guideline number, W- version number)

5.2. Numbering of the Version

Number guideline versions as follows:

- Draft versions:
  All draft versions are always indicated as "version 1.0" followed by the word "draft"
  For example: ***Version 1.0, draft***
- For minor changes on a final version:
  Version V.0, final to ***Version V.n, final***
  For example, the third update concerning minor issues on "version 2.2, final" will be indicated as "version 2.3, final". (n –number of minor changes)(v- version number of the existing guideline)
- For major changes on a final version:
  Version V.n, final to ***Version (V+1).0, final***
  For example, major changes on "version 2.3, final" will be indicated as "version 3.0, final."

5.3. Contents and Layout of a Guideline

A new or updated guideline has five sections:

1. Cover Page
2. Table of Contents
3. Main text
4. References
5. Appendices

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

5.3.1 Cover Page

The cover page will have the following information:

- Logo of EPHI and related information (address, telephone number, fax number, email address, Facebook address, tweeter address)
- Title, number of the guideline and date of implementation of the guideline
- Date of the previous issues. If not applicable, the date of pervious issue is indicated by "N/A" (= not applicable)
- Name (directory names and path included) of the corresponding computer document, if relevant.
  - Name of the editors and address of the contact office.
  - A copyright declaration.
  - Refer to Annex (EPHI-IRB AF 01-002/02.0) 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

Introduction

- Summarize and explain the purpose of the guideline
- A short note on how the guideline was prepared
- A short note on how to use the guideline

Detailed description

- The final text should be short and clear.
- Long guidelines should be split into shorter ones.
- Wherever possible and relevant references should be added
- Limitation of the guidelines may be mentioned

5.3.4 Appendices

- Replace long and complex descriptions.
- "Descriptions-by-example" are always recommended to avoid writing difficult and hard to understand texts.
- Glossary
- Full form of abbreviations

5.4. Approval of New and Updated Guidelines

- The members of the IRB shall prepare a new guideline or update an existing guideline.

- The Chairperson of the IRB and the General Director of the Institute should approve and endorse respectively each new or updated guideline.

5.5. Information for Personnel

- All members of the IRB must read and understand a new or updated guideline
- Each member will sign a form indicating that they have read and understood each new or updated guideline
- If the guideline is for investigators/students/institute personnel then they should be given a copy of the guideline after taking their signature

5.6. Distribution of Guidelines

- Guidelines are not confidential and may be disclosed for use by investigators, scientific experts and IRB members.
- A Log of Guideline Distribution should be maintained for inventory records (Annex 3, EPHI-IRB AF 03-025/2.0).

6. Glossary

Guideline	Any suggestion, rules, etc., intended as a guide for specific practice

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.

8. Annex

Annex 1: Cover Page of a Guideline
(EPHI-IRB AF 01-002/2.0)

Guideline for

……
……

GL#
EPHI-IRB XX.W *(First Edition)*

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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: List of Signatures
(EPHI-IRB 02-002/02.0)

Title of the Guideline: ……..

Number of the Guideline: GL# EPHI-IRB XX.W (XX Guideline number, W- version number)

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

No.	Full Name of IRB members	Signature	Date

Annex 3: Log of Guideline Distribution
(EPHI-IRB AF 03-002/02.0)

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