1.1. Writing, Reviewing, Distributing and Amending Standard Operating Procedures for IRB

Table of Contents

1.1. Writing, Reviewing, Distributing and Amending Standard Operating Procedures for IRB

1. Purpose

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the Institutional Review Board (IRB) of Ethiopian Public Health Institute (EPHI). The SOPs will provide clear, unambiguous instructions so that the related activities in the IRB are conducted in accordance with the WHO Operating Guidelines for IRB that Review Biomedical Research, International guidelines for Biomedical research involving human subjects (Council for International Organizations of Medical Science), National Research Ethics Review Guideline, 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 of EPHI.

3. Responsibility

It is the responsibility of the secretariat of IRB/Scientific Ethical Review Office (SERO) to appoint the SOP Team to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the institute.

3.1. Secretariat of IRB/SERO:

- Coordinates activities of writing, reviewing, distributing and amending SOPs
- Maintains on file all current SOPs and the list of SOPs
- Maintains an up-to-date distribution list for each SOP distributed
- Distributes the SOPs with a receipt to all users
- Ensures all IRB members and involved administrative staff have access to the SOPs
- Ensures the IRB members and involved staff are working according to current versions of SOPs

3.2. SOP team:

- Proposes required SOPs
- Selects the format and coding system
- Drafts the SOP in consultation with IRB members and involved administrative staff

- Assesses the request for SOP revision in consultation with the secretariat/SERO and Chairperson

3.3. Chairperson of the IRB:

- Reviews and approves the SOPs
- Signs and dates receipt of the approved SOPs

3.4. Director General

- Endorse approved SOP

3.4. IRB members and involved administrative staff:

- Sign and date when they receive the approved SOPs
- Maintain a file of all SOPs received
- Return all out-of-dated SOPs to IRB secretariat

4. Flow chart

No.	Activity	Responsibility
1	List all relevant SOPs ↓	SOP Team
2	Design a format and layout ↓	SOP Team
3	Write and approve a new/revised SOPs ↓	SOP Team and Chair person
4.	Endorsement of SOPs ↓	Director General
5	Implement, distribute and file all SOPs ↓	IRB secretariat
6	Review and revise existing SOPs ↓	SOP Team /IRB members/ administrative staff/chair person
7	Manage and archive superseded SOPs	Administrative staff (IRB secretariat)

5. Detailed instructions

5.1. List all relevant SOPs

- Write down step by step all IRB procedures.
- Organize, divide and name each process.
- Make a list of SOPs with coding reference, effectivity and expiry dates (Annex EPHI-IRB AF 01-001/02.0).

5.2. Format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format EPHI-IRB SOP/XXX/YY.W will be assigned to each SOP item by Secretariat/SERO. XXX is a three-digit number assigned specifically to the SOP. YY is a two-digit number identifying the version of the SOP, and W is a one digit number identifying the version of SOP with minor changes in the SOP. The number of version should be started from 01 and the W should be started with 0, for example, EPHI-IRB SOP/001/02.0 is the SOP number 001 version 02 with zero minor revision ie. 02.0.

Each Annex will be given unique code number with the format EPHI-IRB AF BB-XXX/YY.W. AF is the abbreviation for Annex Form, BB is a two-digit number identifying the number of the annex, for example EPHI-IRB AF 01-001/02.0 means Annex Form number one of the EPHI-IRB SOP/001/02.0

Each SOP will be prepared according to the standard template. Please refer to Annex 2 – EPHI-IRB AF 02-001/02.0. Each SOP will contain standard structure containing Purpose, Scope, Responsibility, Flow Chart, Detailed instructions, Glossary, Reference and Annex (See Annex 3 EPHI-IRB AF 03-001/02.0).

5.3. Write and approve a new/revised SOP

If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form (Annex 4 – EPHI-IRB AF 04-001/02.0).

When the need for a new SOP has been identified and agreed on, a draft will be written by a designated member of the SOP team. The draft SOP will be discussed with IRB members and all relevant administrative staff. The SOP should be agreed upon by the

people involved in that particular task. The final version will be passed to the Chairperson for review and approval; and Director General for endorsement.

5.4. Implement, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date. The approved SOPs will be distributed to the IRB members and the relevant staff by the Secretariat/SERO according to the distribution list (Annex 5 – EPHI-IRB AF 05-001/02.0). The SOP will also be uploaded to EPHI-IRB Webpage developed in EPHI Website. When revised version is distributed, the old version will be retrieved and destroyed.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the secretariat of the IRB and keep the file in the secretariat office.

5.5. Review and revise an existing SOP

- Any member of the IRB, secretariat/SERO or administrative staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in Annex 6 – EPHI-IRB AF 06-001/02.0) to make a request.
- If the SOP Team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the person who made the request of the decision.
- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section 5.3).
  The secretariat office/ SERO will identify issues that require minor changes and submit to the IRB for approval and endorsement.
- The Secretariat/SERO is expected to organize the SOP review team to revise the SOPs within a maximum of three years following endorsement by the Director General of the institute and record the dates of review on the SOP Master file.

5.6. Manage and archive superseded SOPs

- Superseded SOPs should be retained and clearly marked “superseded” and archived in the historical file by the secretariat**.**

6. Glossary

IRB members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IRB membership). These boards are constituted in accordance with the EC membership requirements set forth in ICH GCP.
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 (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.
SOP Team	A selected committee of the institute members and administrative staff who oversee the creation, preparation, review and periodic revision of the institute SOPs.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.

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: List of EPHI-IRB SOPs
(EPHI-IRB AF 01-001/02.0)

No.	List of SOPs.	Code	Version	Effective date
1	Writing, Reviewing, Distributing and Amending Standard Operating Procedures for IRB	EPHI-IRB-001	02.0	30 August 2019
2	Preparation of Guidelines	EPHI-IRB-002	02.0	30 August 2019
3	Constituting Institutional Review Board	EPHI-IRB-003	02.0	30 August 2019
4	Confidentiality / Conflict of Interest Agreements	EPHI-IRB-004	02.0	30 August 2019
5	Training Personnel and IRB Members	EPHI-IRB-005	02.0	30 August 2019
6	Selection of Independent Consultants	EPHI-IRB-006	02.0	30 August 2019
7	Management of Protocol Submission	EPHI-IRB-007	02.0	30 August 2019
8	Use of Study Assessment Form	EPHI-IRB-008	02.0	30 August 2019
9	Exemption of protocol review	EPHI-IRB-009	02.0	30 August 2019
10	Expedited Review	EPHI-IRB-010	02.0	30 August 2019
11	Initial Review of Submitted Protocol	EPHI-IRB-011	02.0	30 August 2019
12	Review of New Medical Device Study/Evaluation	EPHI-IRB-012	02.0	30 August 2019
13	Review of Resubmitted Protocol	EPHI-IRB-013	02.0	30 August 2019
14	Review of Protocol Amendments	EPHI-IRB-014	02.0	30 August 2019
15	Management of Protocol Continuing Reviews	EPHI-IRB-015	02.0	30 August 2019
16	Review of Final Reports	EPHI-IRB-016	02.0	30 August 2019

No.	List of Sops.	Code	Version	30 August 2019
17	Intervention in Protocol Deviation/Non-compliance/Violation	EPHI-IRB-017	02.0	30 August 2019
18	Response to Research Participants' Requests	EPHI-IRB-018	02.0	30 August 2019
19	Management of Study Termination	EPHI-IRB-019	02.0	30 August 2019
20	Review of Serious Adverse Event (SAE) Reports	EPHI-IRB-020	02.0	30 August 2019
21	Site Monitoring Visits	EPHI-IRB-021	02.0	30 August 2019
22	Agenda Preparation, Meeting and Minutes Taking Procedures	EPHI-IRB-022	02.0	30 August 2019
23	Emergency Meeting	EPHI-IRB-023	02.0	30 August 2019
24	Communication Records	EPHI-IRB-024	02.0	30 August 2019
25	Maintenance of Active Study Files	EPHI-IRB-025	02.0	30 August 2019
26	Archive and Retrieval of Documents	EPHI-IRB-026	02.0	30 August 2019
27	Maintaining Confidentiality of IRB's Documents	EPHI-IRB-027	02.0	30 August 2019
28	Auditing and Inspection of the IRB	EPHI-IRB-028	02.0	30 August 2019
29	Glossary of Terms and Definitions	EPHI-IRB-029	02.0	30 August 2019

Annex 2: Standard Operating Procedures Template
(EPHI-IRB AF 02-001/02.0)

www.ephi.gov.et	**Ethiopian Public Health Institute** **Institutional Review Board (EPHI-IRB)** SOP Serial No. and Title	EPHI-IRB SOP/XXX/YY.W Effective date: Page - of -

Table of Contents

Annex 3: SOP main contents and definitions
(EPHI-IRB AF 03-001/02.0)

1. **Administrative staff**: Technical staff working for EPHI-IRB secretariat office
2. **Purpose** - summarizes and explains the objectives of the procedure.
3. **Scope** – states the range of activities that the SOP applies to.
4. **Responsibility** – refers to person(s) assigned to perform the activities involved in the SOP
5. **Flow chart** – simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity
6. **Detailed instructions** – describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.
7. **Glossary** – clarifies uncommon or ambiguous words or phrases by explanation.
7. **References** – lists sources of the information given in the SOP.

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

Annex 4: Document History
(EPHI-IRB AF 04-001/02.0)

The first draft for version 02.0 of EPHI-IRB SOP history should 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; and endorsement by the Director General

Author	**Version**	**Date**	**Describe the main change**
SOP Team			
Dr Getachew Addis Mrs Akberet Lemlem Mr. Ibrahim Kedir	02.0	01 May - 07 June 2019	Addressing FERCAP/SIDCER recommendations
Mr. Girum Taye	02.0	8-10 June 2019	Version 1of EPHI-IRB SOPs were revised based on experiences of the IRB and SERO during two years implementation period; SIDCER recommendations and finals report. Accordingly, two new SOPs (Protocol exemption; and archiving & retrieval of documents) were included in addition to the content and topographic revision on Version 1 SOPs.
Mr. Ashenif Tadele			
Dr. Asfaw Debella			
Mrs. Akberet Lemlem			
Mr. Ibrahim Kedir			
Dr. Baye Ashenafi			
Dr. Getachew Addis			
Mr. Ibrahim Kedir	02.0	11 June -29 July 2019	Editorial activities
Dr. Getachew Addis			
Mr. Ibrahim Kedir		03-29 August 2019	Editorial activities
Dr. Getachew Addis			
Mrs. Akberet Lemlem			

Annex 5: Log of SOP Recipients
(EPHI-IRB AF 05-001/02.0)

No.	Name of Recipients	SOP#	No. of Copies	Signature	Date

Annex 6: Request for Revision of an SOP
(EPHI-IRB AF 06-001/02.0)

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.

EPHI-IRB 001/02.0		
Title:	Ethiopian Public Health Institute -Institutional Review Board SOPs (EPHI-IRB SOPs) 30 August 2019, Second Edition	
Details of problems or deficiency in the SOP:		
Identified by:		Date (DD/MM/YYYY):
Discussed with:		
SOP revision required:	☐ Yes	☐ No
If yes, to be carried out by whom?		
If no, why not?		
Date SOP re-finalized:	DD/MM/YYYY	
Date SOP approved:	DD/MM/YYYY	
Date SOP is endorsed	DD/MM/YYYY	
Date SOP becomes effective:	DD/MM/YYYY	