11.1. Glossary of Terms and Definitions

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11.1. Glossary of Terms and Definitions

1. Purpose

This SOP provides guidance regarding definition of terms, abbreviations and titles used by the Institutional Review Board IRB and its administrators to facilitate use and understanding of the IRB Standard Operating Procedures and activities

The definitions are divided into two sections:

- Description/definition of individual roles as used in the IRB SOPs
- Description/definition of terms and abbreviation used in the IRB SOPs

2. Scope

This section applies to all IRB SOPs and activities in addition to persons preparing and/or using the SOPs.

3. Responsibility

It is the responsibility of the IRB members to define or determine and approve the appropriateness of the description.

4. Flow chart

No.	Activity	Responsibility
1	Description of individual titles and roles	IRB members and Secretariat
	↓	
2	Definition of terms	IRB members and Secretariat
	↓	
3	Addition / Correction of new titles and terms	IRB members and Secretariat
	↓	
4	Approval of the new addendum	IRB members / Chairperson

5. Detailed instructions

5.1 Description of individual roles

Chairperson

A member of the IRB who presides over a board meeting. He/she is also responsible for exemption from review and expedited protocol approvals on behalf of the board.

Coordinator (Site)

The person at the study site who is responsible for managing the study. sometimes, the Principal Investigator is also the site coordinator and manager.

IRB

The IRB is a body established to review and monitor health research involving human subjects. The primary purpose of such a review is the protection of the rights and welfare of the human subjects. In accordance with applicable national/international regulations, the IRB has the authority to approve, require modifications to, or disapprove research.

The IRB consists of at least one board with at least ten regular members in addition to ten alternate members. Alternates are categorized and given equal status as regular members within the board (i.e., non-scientific or M.D, etc.). The composition of the membership must reflect a diversity of backgrounds sufficient to assure:

- expertise and experience to provide adequate review of research activities
- consideration of race, gender, and cultural backgrounds
- sensitivity to attitudes and concerns of the community and the patient population
- knowledge of applicable regulation, laws and standards of professional conduct and practice
- no member participates in the review process of any study project in which he/she has a conflicting interest
- no gender discrimination

IRB Members

Employee or nonemployee individuals serving as regular and alternate members in Ethiopian Public Health Institute's review board. This board is constituted in accordance with the IRB membership requirements. Individuals qualified to vote at a duly convened EPHI-IRB meeting.

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Non-Local IRB Review

Under certain circumstances, local review by an Institutional Review Board (IRB) may not be available, e.g., research conducted by investigators unaffiliated with an institution with an IRB. Local regulatory agencies such as FMHACA may allow review of research by IRBs in locations other than where the research is to be performed (e.g., independent IRB or commercial IRB). Therefore, an IRB may review studies that are not performed on-site as long as the requirements are met.

Principal Investigator

Individual responsible for implementing and coordinating an investigational study.

Secretariat

Staff of the Scientific and Ethical Review Office (SERO) of Ethiopian Public Health Institute who are responsible for the day-to-day administrative functions and duties, which support the activities and responsibilities of EPHI-IRB. Nomenclature of the office can however be changed as found appropriate by the institute.

Scientific and Ethical Review Office

An office that serves as secretariat of EPHI-IRB

SOP Team

A selected group of EPHI members and administrative staff who prepare, review and periodically revise the IRB SOPs.

Vice Chairperson

A member of EPHI-IRB who assists the Chairperson as needed in conducting meetings and expedited review

Vulnerable subjects

A category of research participants that includes children, prisoners, pregnant women, handicapped or mentally disabled persons and economically or educationally disadvantaged persons and patients with diseases associated with stigma who are likely inclined to coercion or undue influence

5.2. Definition of Terms

Active study files

Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the *EPHI* IRB.

Administrative documents

Documents include official minutes of Board meetings as described in SOPEPHI IRB meeting minutes and voting records and the standard operating procedures, both historical files and Master Files as described in the SOP, SOP distribution, implementation and file maintenance.

Closed files

Supporting and approved documents (protocols, protocol amendments, informed consents, announcements, investigator and site information), records containing communication and correspondence with the investigator, and reports (including but not limited to progress reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the EPHI-IRB for which a final report has been reviewed and accepted. Closed files are archived for a minimum of three years following completion of the study. These files can be retrieved as needed.

Complementary food

Foods other than breast milk or infant formula introduced to an infant to provide required nutrients to meet the need of an infant.

Deviation

Any instance in which the current approved *EPHI* SOP cannot be or has not been followed.

Expedited approval

An IRB approval granted only by the Chairperson of the EPHI IRB or a designated *EPHI* IRB member (not the full Board) for “minor” changes to current IRB-approved research activities and for research which involves no more than minimal risk

Final report

An obligatory review of study activities presented as a written report to the *EPHI* IRB after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution.

Complete, comprehensive written description of a completed trial that describes the experimental materials and statistical design, presentation and evaluation of the trial results and statistical analyses.

Historical file

A document file which was effectively used in the past and presently became obsolete or expired, but still had to be kept in a file for reference purposes.

Inactive study files

Study protocols declared "Inactive" by EPHI-IRB after six months period of no communication following expire date of approval. Inactive study files are archived for a minimum of five years following approval expire date.

Investigational medical device

A medical device which is the object of clinical research to determine its safety or effectiveness

Investigational New Drug (IND)

Investigational new drug means a new substance, or biological product that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part

Master files

Original copies of documents such as SOPs, guidelines, instruction, manual with real signatures of preparers, reviewers and authorized persons are systematically stored in secured cabinets with limited access.

Medical device

A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-occular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for *in vitro* diagnosis of disease and other conditions, (for example, pregnancy).

Minutes

The official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) independent board review meeting. The minutes identify fully each protocol and/ or activity and record the outcomes of each voting action. The board votes separately on each

collective set or each item submitted for review: protocol, consent form, investigator, and advertisement(s). The record notes the number for, number against, the number of abstaining votes, and the reason for the abstention(s), without identifying the individual member's names.

New study

A study protocol including the informed consent, investigator's qualifications, information on the drug or device and advertisements (if applicable) presented to EPHI for approval for the first time and not previously approved by this Board. This includes re-application for those studies denied approval by EPHI

Non-compliance record

A list containing the identity of investigators who are considered by the Board to be non-compliant with national/international regulations or who fail to respond to the Board's requests, and the incident(s) justifying the reason for the determination of non-compliance.

Non-significant Risk Device (NSR)

A non-significant risk device is an investigational device that does not pose a significant risk.

Progress Report

An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the *EPHI* IRB. Generally, these reports are due annually with the *EPHI* sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the *EPHI* IRB.

Protocol Amendment

A change to the study protocol during the planning or course of the trial
The amendment is a foreseen change to the study plan that requires formal approval by the sponsor.

Quorum

Attendance required to arrive at a decision at any convened meeting of the board. If 10 is the minimum number of members prescribed in the SOP, 6 of the regular and alternate members, which must include at least one non-affiliated and one non-scientist constitutes a quorum and should be maintained throughout the discussions and voting portions of the meeting.

Significant Risk Device (SR)

A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject, (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the subject, (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the subject, or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participants.

Supplementary food

Food which is energy and nutrient dense prepared to treat malnourished person (those at risk) in addition to household ration.

5.3 Addition / Correction of terms

- Members are encouraged to propose any additional terms or make correction of any terms defined in this SOP at any time, if he/she feels clarification should be made.
- Write your proposal.
- Submit your proposal to the IRB secretariat.

5.4 Approval of the addendum

- IRB secretariat shall bring the proposal to a meeting.
- The proposal shall be discussed for further opinion.
- Agreement and approval shall be made at the meeting.

6. Glossary

None

7. Reference

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

None