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1. Purpose

The Institutional Review Board of Ethiopian Public Health Institute is established in order to provide independent guidance, advice, and decision on health and nutrition or related research protocols. The IRB is particularly indebted to safeguard the dignity, rights, safety and wellbeing of human study participants.

The IRB is composed of both scientists and non-scientists. It is independent in its reflection, advice, and decision.

This standard operating procedure describes the Terms of Reference (TOR) which provides the framework for constitution, responsibilities and activities of the IRB. It lays basis for the IRB on how to review health and nutrition research projects that involve human participants; human biological materials; animals;non-biological samples; and data in conformity with institutional, national and international guidelines. It is further supported by the relevant Standard Operating Procedures issued by the IRB.

2.Scope

The SOP applies to members, personals and all activities under the IRB.

3.Responsibility

It is the responsibility of the IRB members and secretariat to read understand and respect the rules set by the IRB.

4.Flow chart

No.	Activity	Responsibility
1	Ethical basis / Guidelines	IRB Members and Secretariat
	↓	
2	Composition of the IRB	IRB Members and Secretariat
	↓	
3	Membership Requirements	IRB Members and Secretariat
	↓	
4	Resignation, Disqualification, Replacement of Members	IRB Members and Secretariat
	↓	
5	Independent Consultants	Chairperson
	↓	
6	Conditions of Appointment	IRB Members and Secretariat
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7	Officers ↓	IRB Chairperson and Vice-Chairperson
8	Secretariat ↓	IRB Secretary
9	Roles and Responsibilities of IRB Members ↓	IRB Members and Secretariat
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11	Quorum Requirements ↓	IRB Members and Secretariat
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13	Dissolving of the IRB	IRB Members and Secretariat

5. Detailed Instructions

5.1. Ethical and Scientific basis

- The IRB is guided in its reflection, advice, and decision by the ethical principles expressed in the national and institutional guidelines and procedures
- It makes further reference to *International Ethical Guidelines: Declaration of Helsinki (1964 and subsequent revisions), guideline for Biomedical Research Involving Human Subjects* (CIOMS), the *Belmont Report*, the European *Convention on Human Rights and Biomedicine*, *WHO* Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, the WHO and ICH Guidelines for Good Clinical Practice
- In evaluating protocols and ethical issues, the IRB is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed Ethiopian Public Health Institute research is being considered
- The IRB recognizes that the protocols it approves may also be approved by national and/or local ethics committees prior to their implementation in specific localities
- The IRB also seeks to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research it has approved.
- The IRB seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations

5.2. Composition of the IRB

- The IRB is composed of not less than 10 voting members and 10 alternate voting members.
- The members shall include at least one member, whose primary concerns are in medical science, at least one member whose primary concerns are in non-scientific areas, at least one non affiliated member from outside the institute and at least one community representatives.
- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the institute.
- Professional qualifications may include public health experts, biologist, physician, pharmacist, nutritionist, environmentalist, epidemiologist, nurse, sociologist, social worker, lawyer, statistician and layperson.
- The IRB cannot consist entirely of men or entirely of women.
- The IRB should have representatives from the senior (eight years and more research experience) and junior (less than eight years research experience).

5.3. Membership requirements

- The head of the institution is responsible for making the appointment of committee members
- Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IRB's work
- Members will be required to sign a confidentiality agreement at the start of their term
- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IRB in the course of its work
- Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration
- The IRB will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision, refer to EPHI-IRBSOP/004/02.0 - Confidentiality/Conflict of Interest Agreement
- Members are appointed for a period of threeyears
- Their appointments may be renewed by the head of Institute for up to two consecutive terms
- At least one-third of the former members should be retained at every point in times to ensure continuity within the IRB

- For a permanently employed secretariat, tenure is not limited provided that he/she is still under the employment of the institute. If, in the event of additional qualified personnel being hired/trained, this time limit may need to be reviewed

5.4. Resignation, Disqualification and Replacement of Members

- Members may resign their positions by submitting a letter of resignation to the Chairperson
- Members may also be disqualified from continuance should the Chairperson provide to members good cause in written arguments warranting disqualification such as breach of confidentiality, breach of conflict of interest and other grave misconduct
- Members that have resigned or have been disqualified may be replaced by appointing authorities

5.5. Independent Consultants

- The IRB may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants
- Independent Consultants are proposed by the IRB and appointed by the chairman
- Their professional qualifications may be in the areas of public health biomedical research, community and/or patient representation, medicine, statistics, social science, law; ethics, religion(see EPHI-IRB SOP/006/02.0)

5.6. Conditions of Appointment

- Members and Independent Consultants are appointed to the IRB under the following conditions:
  - Willingness to publicize his/her full name, profession, and affiliation
  - All financial accountability, reimbursement for work and expenses, if any, within or related to the IRB should be recorded and made available to the public upon request
  - All IRB and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters
  - IRB members need to sign commitment form (EPHI-IRB AF 01-003/02.0) to serve with diligence for one term (three years)

5.7. Officers

The following officers through their respective responsibilities contribute to the good functioning of the IRB:

Chairperson

- The General Director of Ethiopian Public Health Institute shall appoint the chairperson of the IRB.
- Responsible to chair the meetings and liase directly with the General Director of Ethiopian Public Health Institute.
- Report the meeting outcomes to the General Director.
- Propose independent consultants to provide special expertise to the IRB on proposed research protocol.
- Assign an IRB member in writing or through email making CC to all IRB members to chair a particular full board meeting when both the Chairperson and Vice-Chairperson cannot attend the meeting.
- The Chairperson should have the authority to sign official IRB documents such as approval certificates.
- Should the Chairperson decide to step down as Chairperson of the IRB, he/she should inform the head of the institute and IRB in writing at least one month in advance; the committee is obliged to inform the appointing authority.

Vice-Chairperson

- The vice- Chairperson should be selected by the IRB members through a process of nominations followed by secret ballot voting.
- Responsible to chair the meetings in the absence of the Chairperson and act as vice-chair during meetings with the Chairperson.

Secretary

- The secretary of the IRB will be a permanent staff from SERO.
- Responsible for the administrative aspect of the IRB (see 5.8 - below).

- The officers (Chairperson and Vice-Chairperson) appointed and elected for three-year term. They may be re-appointed or re-elected but not for more than two consecutive terms. Should the Chairperson or Vice-Chairperson

resign or be disqualified, General Director appoint and IRB members elect a replacement, respectively, until the completion of the normal term

5.8. Secretariat

- SERO shall be the secretariat of the IRB and is composed of the IRB secretary and the administrative supporting staffs.
- The Secretariat shall have the following functions:
  - Organizing an effective and efficient tracking procedure for each proposal received (see EPHI-IRB SOP/007/02.0, EPHI-IRB SOP/025/02.0)
  - Preparation, maintenance and distribution of study files (see EPHI-IRB SOP/025/02.0)
  - Organizing IRB meetings regularly (EPHI-IRB SOP/022/02.0).
  - Preparation and maintenance of meeting agenda and minutes (see EPHI-IRB SOP/022/02.0)
  - Maintaining the IRB's documentation and Archive (See EPHI-IRB SOP/025/02.0 and EPHI-IRB SOP/026/02.0)
  - Communicating with the IRB members and applicants (EPHI-IRB SOP/024/02.0)
  - Arrangement of training for personnel and IRB members (see EPHI-IRB SOP/002/02.0)
  - Organizing the preparation, review, revision and distribution of SOPs and guidelines (see EPHI-IRB SOP/001/02.2 and EPHI-IRB SOP/025/02.0)
  - Providing the necessary administrative support for IRB related activities to the Chairperson of the Committee (e.g. communicating a decision to the applicant - EPHI-IRB SOP/007/02.0 – EPHI-IRB SOP/021/02.0.)
  - Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

5.9. Roles and responsibilities of IRB members

- Membership becomes effective upon accepting an invitation from the appointing authority. Acceptance must be indicated by the member's dated signature
- A member should be willing to have his/her full name, profession and affiliation(s) published in the public domain
- Participate in the IRB meeting
- Know any relevant SOPs of the IRB
- Review, discuss and consider research proposals submitted for evaluation

- Monitor serious adverse event reports and recommend appropriate action(s) (EPHI-IRB SOP/018/02.0)
- Review the progress reports and monitor ongoing studies as appropriate
- Evaluate final reports and outcomes
- Maintain confidentiality of the documents and deliberations of IRB meetings (EPHI-IRB SOP/024/02.0)
- Declare any conflict of interest
- Participate in continuing education activities in biomedical ethics and biomedical research

5.10. IRB Meetings

- The committee meets every two weeks regularly. The Chairman however, in consultation with the Secretariat, may call an extra ordinary meeting at any time if deemed necessary

5.11. Quorum Requirements

- More than 50% of the members must be present at a meeting in order to issue a valid advice and/or decision
- Professional qualifications of the quorum requirements should consist of:
  - At least one member whose primary area of expertise is in a non-scientific area, and one scientist
  - And at least one member who is outside of the institute i.e community representative or a person who is non-affiliated to the institute

5.12. Voting System

- Decisions will be made on a consensus basis. Whenever there is a difference among committee members that cannot be resolved by discussion, decisions will be made by simple majority votes; all members have equal voting rights. When votes are at par, the decision the Chair person supports will be final

5.13. Dissolving of the IRB

- At any point in time, should the Ethiopian Public Health Institute cease to exist, the IRB is automatically dissolved.
- The IRB may also be dissolved at any time by the Director of the Ethiopian Public Health Institute, following written notification to each of the members.

6. Glossary

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IRB's information and documents
IRB	Institutional Review Board is an independent body (board) whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Scientists	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed
SERO	Scientific and Ethical Review Office

7. References

1. FDRE Ministry of Science and Technology, National Research Ethics Review Guideline, 2014.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.
3. Relevant SOPs: EPHI-IRB SOP/001/02.0, 004/02, 005/02, 007/02.0-023/02.0, 025 and 029.
4. World Health Organization, Standards and Operational Guidance for EthicsReview of Health-Related Research with Human Participant, 2011.

8. Annex

Annex 1:EPHI-IRB Members Commitment Form
(EPHI-IRB AF 01-003/02.0)

Date: ……..…….

I the undersigned acknowledge Ethiopian Public Health Institute (EPHI) for nominating me to serve as member of the institutional review board of the institute (EPHI-IRB). I have accordingly meticulously read the Term of Reference (TOR) of EPHI-IRB and get cognizant of the vital roles and responsibilities of board members in doing ethical and quality health and nutrition related research being conducted in Ethiopia by EPHI and other institutions who submit protocol for review and determination by the IRB. I am particularly aware of the following tasks of IRB members:

- Attend and actively participate in convened and emergency EPHI-IRB meetings,
- Participate in a discussion of all agenda items for each convened IRB meeting,
- Review protocols as primary or secondary reviewer based on the assessment form (EPHI-IRB AF 01-008/02.0) and submit one completed form to secretary of the IRB,
- When acting as primary reviewer, will exert effort to resolve questions or concerns prior to the meeting, which may necessitate contacting principal investigator/ designee,
- Primary reviewer provides debriefing about the issues, concerns and questions about scientific, ethical and other relevant matters on the protocol that he/she reviewed and present his/her suggestions and recommendations in the IRB meeting,
- Primary reviewer leads the discussion on a protocol for which he/she was assigned to review,
- Provide a written review summary to the secretary prior to the meeting, if assigned as primary reviewer and unable to attend the meeting,
- All IRB members will receive review package of each protocol; further review the documents to their capacity; raise their own questions and other concerns; and forward their suggestions and recommendations during the convened IRB meeting,
- Keep abreast of Research Ethics, Good Clinical Practice, National and International Research Ethics Guidelines that govern IRB review and determination and the conduct of research on human research participants,
- Participate in IRB educational activities,

- If a member will be unable to attend scheduled IRB meeting, he/she will inform the secretary at least three days prior to the meeting for appropriate subsequent corrective action, and
- Other relevant activities indicated in the TOR of the IRB and when requested by the IRB and/or Chairperson

I therefore reiterate that I am well aware of the roles and responsibilities of members of EPHI-IRB, which are described above and others indicated in the TOR. I gladly accept my appointment as member of EPHI-IRB and express my commitment to contribute with my utmost capacity at least for one term (three years) as of my recent appointment.

Name of IRB Member: ……..……

Signature: ……

Date: ……..