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1. Purpose

This standard operating procedure describes how the Institutional Review Board (IRB) manages to review an initially submitted protocol.

2. Scope

This SOP applies to the review process of the study protocol package submitted for the first time.

3. Responsibility

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments to the IRB in the Assessment Form and return to the Secretariat Office on the date due.

The IRB Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version of the received packages. In addition, the secretariat should create a protocol specific file, distribute the packages and get them reviewed by the IRB and deliver the review results to the applicants.

4. Flow chart

No.	Activity	Responsibility
1	Receive the application protocol package	IRB Secretariat
	↓	
2.	Decide Protocols to be reviewed by EPHI-IRB and refer to NRERC	IRB chairperson
	↓	
3	Decide for exempted, expedited or full-board review by EPHI-IRB	IRB chairperson
	↓	
4	Assign/decide reviewers	Chair person
	↓	
5	Receive protocol for reviewing	Reviewers
	↓	
6	Verify the contents of the package	Reviewers
	↓	

7.	Review the protocol based on the assessment form ↓	Reviewers
8	Communicate with secretariat office ↓	IRB Secretariat/IRB member/Reviewers
9	Discuss inIRB meeting ↓	IRB members/Reviewers/ IRB Secretariat
10	Final communication of the decision ↓	IRB secretariat/ Chairperson
11	Documentation	IRB Secretariat

5. Detailed instructions

5.1.Receive the application protocol packages (EPHI-IRB SOP/007/02.0)

- Check the submitted packages for completeness
- Receive Memorandum of Understanding (MoU) among collaborating parties for projects to be executed by two or more institutions
- Receive Material Transfer Agreement (MTA) between provider and recipient institutions for any biological material to be exported outside Ethiopia
- Contact applicant if not complete/ or additional information needed
- Receive full package protocol

5.2.Decide on protocols to be reviewed by National Research Ethics Review Committee (NRERC)and EPHI-IRB

5.2.1 Protocols referred to National Research Ethics Review Committee (NRERC): Protocols on human genetic research; stem cell research; new devices for scaling up andclinical evaluations/trials of medicines and vaccines that are not registered for use in Ethiopia; protocols funded by manufacturers and pharmaceutical companies will be referred to NRERC

5.2.2 Protocols reviewed by EPHI-IRB: All protocols on health, nutrition and related areas except those indicated on 5.2.1 will be reviewed by EPHI-IRB.

5.3.Decide for exempted, expedited or full-board review of protocols within the mandate of EPHI-IRB

- The IRB chairperson determines the protocols to be reviewed through exempted, expedited process or full board review. The chairperson can however take submitted protocol to a full board meeting for determination, if he/she found it appropriate.

5.4. Assign reviewer/s

- Identify appropriate reviewer/s based on the expertise required to review the protocol
- Send complete package protocol to the reviewer with the assessment form

5.5. Receive protocol for reviewing

- Check the received packages for completeness
- Sign and date an acknowledgement form upon receiving the packages.
- Return the receipt form back to the IRB secretariat

5.6. Verify the contents of the package

- Look for an Assessment Form EPHI-IRB AF 01-008/02.0
- Check the meeting date to see if he/she is available to attend the meeting
- Notify the IRB Secretariat if there are documents missing, or the specified date cannot be met.

5.7.Review the Protocol

5.7.1 Initial Review Application Form

- Check the form for completeness of the information and signatures of the principal investigator
- Check and attach the Initial Review Application Form EPHI-IRB 01-011/02.0) to the Research Protocol.

5.7.2 Assessment Form

- Use the Assessment Form EPHI-IRB AF 01-008/02.0 to guide the review and deliberation process.

  Note: The completed Assessment Form is the official record of the decision reached by the IRB for the specific protocol.
- Consider the following criteria when performing the review:

- minimize risks to participants
- risks must be reasonable in relation to anticipated benefits;
- participants are selected equitably
- informed consent is adequate, easy to understand and properly documented
- the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate
- there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate and
- appropriate safeguards are included to protect vulnerable participants
- Other pertinent issues

- Make comments where appropriate
- Sign and date the reviewer's name
- Report your final remarks on the protocol using Assessment Report Form (EPHI-IRB AF 02-008/02.0)

5.8. Communicate with secretariat office

- Reviewers send their comments made using the assessment form on the protocol to the secretariat
- Principal investigator/designee requested to provide clarifications or answer to unclear issues, if there is/are any, to the secretariat
- Secretariat sends protocol & other relevant documents to IRB members at least three days prior to the IRB meeting for their preparation to convened IRB meeting

5.9.Discuss in an IRB meeting (except exempted: EPHI-IRB SOP/009/02.0; and expedited review:EPHI-IRB SOP/010/02.0)

- The primary reviewer presents a brief oral or written summary of the study design and his/her comments or can be presented by the IRB members/ chairperson in the absence of the primary reviewer(debriefing summary sheet)
- The Chairperson or designee entertains discussion on each document under consideration (e.g., protocol, informed consent, investigator's and site qualifications, advertisements).
- Recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the IRB are noted in the meeting minutes

as 'with modifications made by IRB' and will be communicated to the investigator.

- The chairperson or designee calls for a separate vote on each element in review. The Committee votes to either:
  - Approve the study to start as presented with no modifications
  - Approve the study to start with committee approved modifications to the consent =*Approved with minor revision*
  - Require modifications to items noted at the convened meeting and follow-up by the chairperson, after receipt of the requested modifications = *Approved with minor revision*
  - Require modifications to the items and full board review of the materials = *Major revision or re-submission*
  - Request further information regarding the item and full Committee re-review of the material = *Major revision or re-submission*
  - Do not approve the study, stating the reason for disapproval = *Disapproved*
- If the study is approved, the board determines the frequency of Continuing Review (monitoring) from each investigator.
  - SERO sends an action letter along with the approved documents to the investigator
  - The letter contains, at a minimum, a listing of each document approved, the date set by the board for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study (EPHI-IRB AF 05-008/02.0)
  - A computergenerated approval and expiration date is placed on every page of each consent form approved by theIRB.
- If the board votes not to approve the study, SERO immediately notifies the investigator in writing about the decision and the reason for not approving the study (EPHI-IRB AF 06-008/02.0)
- If the investigator wishes to apply/complain against the decision, he/she may do so by contacting SERO(EPHI-IRB AF 07-008/02.0)
- If the board requires modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the IRB.

5.10.Final Communication of the Decision

5.10.1 Signature of Approval

- Obtain and complete the appropriate forms, after a decision has been reached by the IRB
- Get signature from the Chairperson
- Date the form

5.10.2 Complete the decision report form

- Complete the decision report form
- Get signature of the Chairperson
- Maintain and attach the completed assessment form and the minutes of the meeting relevant to the protocol review
- Process the above tasks *within 5 working days after the meeting*
- Get decision report form

5.10.3 The Action Letter

- Prepare an Action Letter to inform the investigator about the IRB's decision (EPHI-IRB AF 05-008/02.0 and EPHI-IRB AF 06-008/02.0)
- State clearly the actions that need to be taken by the investigator.
- For the decision disapproval, a notifying letter to the investigator or the project manager should state the followings:
- "If you wish apply complain against the decision, please contact theEPHI-IRB and submit your complaint in writing, addressed to the IRB Chairperson with justification as to why the complaint should be granted" (EPHI-IRB AF 07-008/02.0)
- Verify the correctness of the wordings and spelling.
- Send the action letter to the applicant within 10 working days.

5.11.Documentation

- Keep a copy of the Action Letter in the Correspondence file.
- Place the original documents of the Application Review, Assessment Forms and the decision form in sequence of protocol number in the Approved file.
- Document the files on appropriate shelf in the designated cabinet.

6. Glossary

Initial Review	The first-time review of that protocol made by two individual reviewers (IRB members or non-members) in advance of the full board meeting, and comments of the reviewers will be reported to the full board meeting.
Phase I study	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.
Stipulation	Specify as terms of or condition for an agreement, contract, etc. state, put forward for a necessary condition.

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.
3. Ministry of Science and Technology, National Research Ethics Review Guideline, 2014.
4. Relevant SOPs: EPHI-IRB SOP 007/02.0, EPHI-IRB SOP 008/02.0, EPHI-IRB SOP 027/02.0

8. Annex

Annex1: Application form for Initial Review
(EPHI-IRB AF 01-011/02.0)

Protocol Title:	
Protocol number:	Total Participants to be included:

STUDY TYPE: (Mark "✓" whichever apply to the study)

☐ Survey ☐ Social ☐ Medical ☐ Community based ☐ Individual based

☐ Screening ☐ Observational ☐ Epidemiology ☐ Intervention study

☐ Clinical Trial: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

☐ Genetic Study ☐ Retrospective ☐ Prospective ☐

Others……..

STUDY POPULATION:: ☐ Healthy ☐ Patient ☐ Vulnerable groups

CHARACTERISTICS of PARTICIPANTS PARTICIPATED:

AgeRange: ☐ 0 -17 yrs ☐ 18 - 44 yrs ☐ 45 - 65 yrs ☐ ≥ 66 yrs

Pediatric ☐ None ☐ < 1 yr ☐ 1-3 yrs ☐ 4 -14 yrs

Impaired ☐ None ☐ Physically ☐ Cognitively ☐ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:

☐ None ☐ Male ☐ Female ☐ Children ☐ Other (specify))

SPECIAL RESOURCE REQUIREMENTS (check all that apply):

☐ Intensive Care ☐ Isolation unit ☐ Surgery

☐ Pediatric Intensive Care ☐ Transfusion ☐ CAT scan

☐ Gene therapy ☐ Controlled substances(Narcotics/Psychotropics)

☐ Prosthetics ☐ Gynecological services ☐ Others, specify……

☐ Organ transplantation, specify……..

IONIZING RADIATION USE (X-rays, radioisotopes, etc):

☐ None ☐ Medically indicated only

INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):

☐ None ☐IND ☐ IDE

FDA No.:…… FDA No:……

Name:…… Name:……

Sponsor:…… Sponsor:……...

Holder:…… Holder:……...

PROCEDURE USE: ☐Invasive ☐Non-invasive

MULTI-SITE COLLABORATION: ☐ YES ☐ NO

FINANCIAL DISCLOSURE: ☐ YES ☐ NO

INSTITUTE RESEARCH CONTACT

Name:……

Address:……

Telephone:……

Fax:……

E-mail:……...

Annex1: Application form for Initial Review (cont'd)
(EPHI-IRB AF 01-010/02.0)

PARTICIPATING INVESTIGATORS:

Full Name	License No.	Institution	Telephone /e-mail
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

MODE OF REVIEW:

☐ Expedited Review
☐ Full Board review

TYPE OF REVIEW:

☐ Initial Review ☐ Resubmission Review ☐ Amendment Review	☐ Continuing Review ☐ Final Report Review ☐ Protocol Termination

SIGNATURES:

Date: ……..
Principal Investigator

COMPLETION:

Date:……
Secretary,*EPHI-IRB*