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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional **Review** Board (IRB) members will perform an expedited review on a new research study protocol using the Assessment Form (EPHI-IRBAF01-008/02.0)

2. Scope

This SOP applies to the review and approval of research studies and documents, which qualify for expedited review by the SERO/Chairperson. Any protocol that carries not more than minimal risk and fulfills criteria for expedited review) is covered in this SOP.

3. Responsibility

It is the responsibility of the IRBchairperson **to** decide which study protocols should be reviewed and approved through expedited channel.

4.Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents	IRB Secretariat
	↓	
2	Determine protocols for expedited review	Chairperson
	↓	
3.	Nominating reviewers	Chairperson
	↓	
4	Receive protocol package for reviewing	IRB member/Reviewer
5	Review the protocol	IRB member/Reviewer
	↓	
6	Communication with secretariat office	IRB Secretariat/
	↓	IRB member/Reviewer
7.	Taking decision	Chairperson/IRB
	↓	
8.	Communicate with the Investigator	IRB Secretariat
	↓	
9.	Reporting decision to the board	Chairperson/Secretary
	.	

5.Detailed instructions

5.1.Receive the submitted documents

- Receive the application documents submitted by investigators
- 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
- Get a content of submitted package (checklist) form, EPHI-IRB AF 01-007/02.0to check items received
- Stamp the receiving date on the letter and the documents
- Sign the receiver's name on the receiving documents
- Hand the received documents to the IRBsecretariat

5.2.Determine protocols for expedited review

Chairperson determines whether a study is qualified for expedited review according to the following criteria:

- Protocols approved by IRBs in Ethiopia, which obtain accreditation by SIDCER (eg. AHRI & College of Health Sciences of AAU)
- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis
- Research on interventions in emergency situations
- Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use.
    - Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other

routine clinical measurements, exercise tolerance etc. However, procedures involving the use of x-rays or microwaves will not qualify for expedited review, rather, reviewed through initial review (EPHI-IRB SOP/011/02.0)

- Research on disaster management
- Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported
- Proposals involve interviewing of a ***non-confidential nature*** (not of a private eg. relate to sexual preference *etc*.), ***not likely to harm*** the status or interests of the individual and ***not likely to offend*** the sensibilities of the people involved
- Those that involve ***collection of small amounts of blood samples*** (and not too frequent) e.g. by finger, heel or ear stick
- Those that involve collection of biological specimens for research purposes by ***non-invasive means*** (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner)
- Collection of data for research purposes through ***non-invasive procedures*** (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However, procedures involving the ***use of x-rays or microwaves are NOT recommended for expedited review***
- Research involving data, documents or specimens that have been already collected or will be ***collected for ongoing medical treatment*** or diagnosis
- Continuing review of previously approvedprotocols
    - Protocols approved through expedited review process

- Protocols approved through full board review given that:
  - Studies have taken place and ***no additional risks*** have been ***identified***
  - Continuation request is submittedand approval provided for the duration within the project implementation period as depicted in the approval certificate
  - Continuation request beyond implementation time for data analysisand report writing

- Modification /amendment of protocol:

  All protocols approved through expedited review process; and protocols approved through full board review but require amendment on the following specifics:

  - *Administrative revisions*, such as correction of typos, addition or deletion of *non-procedural items*, such as the addition of study personnel names, laboratories, etc.
  - *Non-significant risk* research activity, the research activity includes only *minor changes*from previously approved protocol
  - Other documents which would be considered for expedited review are as follows but may not be restrict to:
    - The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, the research remains active for long term follow up of subjects
    - Where no subjects have been enrolled and no additional risks have been identified
    - Where the remaining research activity are limited to data analysis
    - Minor changesinpreviously approved research during the period (usually of one-year duration) for which approval is authorized
    - Change in the name and address of sponsor
    - Change in contact details of principal investigator

- Request for change in principal investigator and co-investigator
- Minor amendments in the protocol, case record form
- Minor corrections in budget
- Other administrative changes as in the investigator brochure and informed consent form

- If the protocol satisfied any of the criteria for **expedited** review, the secretariat will send the protocol to chairperson for decision.

5.3. Nominating Reviewers

- After determining that the Protocol/Project qualifies for an expedited review, the chairperson will nominate two IRB members or consultants to review the protocol,or, take the protocol to full board meeting for identifying and assigning appropriate reviewer
- The selected membersare normally those who reviewed and recommended the previous version of that protocol, if it is not submitted for the first time
- The reviewer is expected to review and provide feedback within 15 days

5.4. Receive protocol package for reviewing

- Check the received packages for completeness
- Look for an Assessment Form (EPHI-IRB AF 01-008/02.0)
- Sign and date an acknowledgement form upon receiving the packages
- Return the receipt form back to the IRB secretariat

5.5. Review the protocol

- Use Protocol Assessment Form (EPHI-IRB AF 01-008/02.0) to guide the review
- Report your final remarks on the protocol using Assessment Report Form (EPHI-IRB AF 02-008/02.0)

5.6. Communication with secretariat office

- Reviewers send their comments using the assessment form on the protocol to the secretariat
- Secretariat synthesizes reviewers' comments and send to principal investigator/designee
- Secretariat receives feedback to reviewers' comments from the investigator

5.7.Taking decisions

5 .7.1 Decisions by chairperson

- The secretary will discuss with the chairperson on the response to comments of the reviewers
- Further queries may be sent, if there are any, to the PI/designee within two working days after receipt of feedback by the secretariat
- If the two reviewers approved the protocol,final decision will be provided by the chairperson and recorded on Decision Form (EPHI-IRB AF 03-008/02)
- The decision will be informed to the IRB members at the next full board meeting

5.7.2 Decision by full board Review

- If one or both reviewers disapprove the protocol, the chairperson will automatically refer the protocol for full board reviewand decision. Any protocol should only be disapproved by full board meeting
- The chairperson may also refer protocols reviewed and approved by the two reviewers, if he/shefound it necessary,for full board review and decision

5.8. Communicate with the Investigator

- The secretariat will send the study approval letter to the PI

5.9. Report decision at convened meeting

- The chairperson/secretary should informto the IRB about the proposals approved by expedited review at its full board meetings.

7. Glossary

Administrative documents	Documents include official minutes of Board meetings as described in Standard Operating Procedures, both historical and Master Files as described in EPHI-IRB-SOP 027/02.0
Expedited approval	An approval granted only by the chairperson ofEPHI-IRB or a designated board member (not the full Board) for minor changes to current IRB approved research activities and for research which involves no more than minimal risk.
Expedited review	A review process by only two or more designated IRB members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.

8. 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. Code of Federal Regulations (45 CFR 46): Protection of Human Subjects, Department of Health and Human Services, USA, 2009.
4. FDRE Ministry of Science and Technology, National Research Ethics Review Guideline, 2014.
5. RelevantSOPs: EPHI-IRB SOP 007/02.0, EPHI-IRB SOP 008/02.0, EPHI-IRB SOP 027/02.0

9. Annex

None