Table of Contents

1. Purpose

This SOP describes how the IRB members use the assessment forms when reviewing the study protocols initially submitted for approval. The Assessment Form (EPHI-IRB AF01-008/02.0), IRBdecision reportand the action letter aredesigned to standardize the review process and to facilitate reporting, recommendation and comments given to each individual protocol.

2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IRB. The specific questions in the Assessment Form must be adequately addressed in the protocol itself and/or protocol-related documents under review. Relevant points made during discussion and deliberation about a specific protocol should be recorded on the appropriate form. The decision reached by the committee and the reasons for its decision is recorded on the Application Assessment Form.

3. Responsibility

It is the responsibility of the reviewers to fill the assessment form along with decision and comments they might have after reviewing each study protocol. The IRB Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision. The Chairperson of IRB of the EPHI must sign and date to approve the decision in the form.

4. Flow chart

No.	Activity	Responsibility
1	Summarize the protocol in an Assessment Form	IRB Secretariat
	↓	
2	Review the Study Protocol	IRB members / Reviewers
	↓	
3	Examine qualification of Investigators and study sites	IRB members / Reviewers
	↓	
4	Review study participation	IRB members / Reviewers
	↓	
5	Examine community involvement and impact	IRB members / Reviewers
	↓	
6	Make a decision	IRBMembers/Reviewers
	↓	
7	Gather Assessment Reports	IRB Secretariat
	↓	
8	Record the IRB's Decision	IRB Secretariat

5. Detailed instructions

5.1. Summarize the protocol in an Application Assessment Form

Record general information about the protocol in the form EPHI-IRB AF 01-008/02.0 (Annex 1) such as:

- Title of the protocol
- Protocol number and date
- Principal Investigators, license & contact number
- Co-investigators & contact number
- Funding agency & contact number

- Study types
- Duration of the study
- Status of the protocol – New / Resubmitted / Amended
- Mode of review – Full Board / Expedited
- Reviewer's name
- Objective and description of the Study

5.2. Review the study protocol

- Need for human participants for study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and data management
- Inclusion/exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or discontinuation criteria

5.3.Examine the qualification of investigators and of study sites

- Consider whether study and training background of the participating investigators relate to the study.
- Examine disclosure or declaration of potential conflicts of interest
- Can facilities and infrastructure at study sites accommodate the study?
- Non-physician principal investigators (PI) should be advised by a physician when necessary.

5.4. Review study participation

- Voluntary, non-coercive recruitment/participation

- Procedures for obtaining informed consent
- Contents of the patient information sheet
- Contents and language of the informed consent document
- Translation of the informed consent document in the local
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers
- Privacy and confidentiality
- Risks – physical / mental / social
- Benefits – to participants and to others
- Compensation – Reasonable / unreasonable
- Involvement of vulnerable participants
- Provisions for medical/psychosocial support
- Treatment for study related injuries
- Use of biological materials

5.5. Examine community involvement and impact

- Community consultation
- Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
- Contribution to development of local capacity for research and treatment
- Benefit to local communities
- Availability of study results

5.6. The reviewer makes a decision

- Get the assessment report form (EPHI-IRB AF02-008/02.0)
- Record the decision by marking in the desired block any of the following: *"Approved, Approvedwith minor comments, Resubmitted, or Disapproved."*

- Include comments, suggestion and reason for disapproval.
- Check the completeness and correctness of the assessment form.
- Sign and date the decision form.
- Give or send the complete forms to the IRB Secretariat.

5.7. Gather the assessment reports

- Collect the assessment forms and the review result from each reviewer.
- Organize the forms in order
- Summarize the comments, suggestions, and opinions of each study in the meeting agenda
- Follow EPHI-IRBSOP/022/02.0 Preparation of meeting agenda and minutes.

5.8. Record the IRB decision

- Get the IRB's decision form. (EPHI-IRB AF 03-008/02.0), see Annex 3.
- Complete the information. (by the Secretariat)
- List participating members and their votes
- Summarize the guidance, advice and decision reached by the IRB members
- Sign and date the document. (by the Chairperson of the IRB or by the Scientific Director, where applicable)
- Make a copy of the completed decision form
- Keep the original copy in the file labelled "IRB's decision"
- Keep the copy of the decision form with the study protocol
- Return the file and the protocol to the appropriate shelves

5.9. Prepare decision report

5.9.1 Prepare certificate of approval

- Get the IRB decision report
- Complete the information(EPHI-IRB AF05-008/02.0).
- Submit full-fledged document including final protocol, ICF and other relevant documents to the chairperson for signature supporting with signed final document submission verification form (EPHI-IRB AF08-008/02.0)
- Sign and date the certificate of approval by the Chairperson of the IRB and Director General of EPHI
- Assign the EPHI-IRBprotocolnumber by filling in the boxes with numbers in sequential order, “EPHI-IRB-☐☐☐-☐☐☐☐”
- Make a copy of the completed certificate of approval form
- Keep one copy in the file labelled “IRB certificate of approval”
- Keep one copy in the study protocol file
- Provide approval certificate to the PI or delegate of the project

5.9.2 Prepare notification for disapproval

- Get the IRB decision report
- Complete the information(EPHI-IRB AF06-008/02.0).
- Submit full-fledged document including final protocol, ICF and other relevant documents to the chairperson for signature supporting with signed final document submission verification form (EPHI-IRB AF08-008/02.0)
- Sign and date the notification for disapproval form by the chairperson of the IRB and Director General of EPHI
- Make a copy of the notification for disapproval form
- Keep one copy in the file labelled “ IRB notification for rejection”
- Provide notification for disapproval form to the PI or delegate of the project

6. Glossary

Study Assessment Form	An official record that documents the protocol review process.
Document	Document may be of any forms, eg., paper, electronic mail (e-mail), faxes, audio or video tape, etc.
Vulnerable study participants	A vulnerable category of study participant includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

7. References

1. World Health Organization, Standards and Operational Guidance for EthicsReview 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. Ethical Guidelines for Biomedical research on Human Subjects, 2000.
4. Associated SOP:EPHI-IRB SOP/022/02.0

8. Annex

Annex 1:Study Assessment Form
(EPHI-IRB AF 01-008/02.0)

Protocol Number : EPHI-IRB-☐☐☐-☐☐☐☐			Date (DDMM/YYYY):
Protocol Title :			
Principal Investigator:			Contact Tel. Address: Contact Email Address: Relevant credentials:
Institute:			Contact tel. Address: Contact Email Address:
Co – investigator(s):			
Total No. of Participants:		No.of study sites:	
Funding Agency:			Contact Address
Duration of the Study:		Status:	☐ New ☐ Resubmitted ☐ Amended
Reviewer's name :			Contact Tel. Address: Contact Email Address:
Type of the Study :	☐ Intervention ☐ Epidemiology ☐ Observation ☐ Document based ☐ Individual based ☐ Genetic ☐ Social Survey ☐ Others, specify…….		
Mode of Review:	☐Expedited ☐Full Board		

Mark and comment on whatever items applicable to the study.

A. Scientific Issues

1	Title of the protocol ☐clear ☐unclear	Comment:
2	Summary ☐clear ☐unclear	
3	Background and justification ☐ sufficient ☐insufficient	Comment:
4	Availability of similar Study / Results ☐ Yes ☐ No ☐Don't know	Comment:
5	Objectives of the Study ☐ clear ☐ unclear	Comment:
6	Methodology: ☐ clear ☐ unclear	What should be improved?
7	Study tools are annexed? ☐ Yes ☐ No ☐ Not applicable	
8	Study tools are translated to local language? ☐ Yes ☐ No ☐ Not required	
9	Need for Human Study Participants ☐ Yes ☐ No	Comment:
10	Use of Placebo or less effective intervention ☐Justified ☐ Not justified ☐ Not Applicable	Comment:
11	Sufficient number of participants?	Comment:

	☐ Yes ☐ No ☐ Not applicable	
12	Inclusion criteria ☐appropriate☐ inappropriate ☐ not applicable	Comment:
13	Exclusion criteria ☐appropriate☐ inappropriate ☐ not applicable	Comment:
14	Benefits of the study ☐ Clear ☐Unclear	Comment:

B. Ethical and Informed Consent Issues

15	Ethical consideration well described in the protocol ☐Yes ☐No	Comment:
16	Equitable/Justified selection of study participants ☐Yes ☐No	Comment:
17	Equitable/Justified selection of study sites ☐Yes ☐No	Comment:
18	Are procedures for obtaining InformedConsent appropriate? ☐ Yes ☐ No	Comment:
19	Contents of the Informed Consent Document ☐Relevant issues addressed ☐Relevant issues not addressed	Comment:
20	Assent and parental/guardian consent required and obtained? ☐ Yes ☐ No	Comment:

21	Language of the Informed Consent Document ☐Appropriate ☐Not Appropriate	Comment:
22	Provision for Compensation ☐ appropriate ☐ inappropriate	Comment:
23	Voluntary, no undue influence for Participation ☐ Unlikely ☐ Likely	Comment:
24	Voluntary, non-coercive recruitment of participants ☐ Yes ☐ No	Comment:
25	Withdrawal Criteria ☐Described ☐Not Described	Comment:
26	Privacy & Confidentiality maintained ☐ Yes ☐ No	Comment:
27	Risks ☐ Yes ☐ No If yes: What type of risk? ……. What level of risk? ……	Comment:
28	Category of risk/benefit ☐Minimal risk ☐Greater than minimal risk but presenting the prospect of direct benefit to the individual study participant ☐Greater than minimal risk and no direct benefit to the individual study participant but likely to yield generalizable knowledge about participant's disorder or condition ☐ Outside those mentioned above	Comment:

29	Risks are minimized? ☐ Yes ☐ No	Comment:
30	Provision for Medical / Psychosocial Support ☐ appropriate ☐ inappropriate	Comment:
31	Provision for Treatment of Study-Related Injuries ☐ appropriate ☐ inappropriate	Comment:
32	Benefits? ☐Yes ☐ No	Comment:
33	Is there benefit to the individual? ☐Yes ☐ No	Comment:
34	Benefit to local communities ☐ Yes ☐ No	Comment:
35	Use of vulnerable participants ☐Justified ☐ Not justified	Comment:
36	Measures to protect vulnerable participants ☐Sufficient ☐ Not sufficient	Comment:
38	Community Consultation ☐ Yes ☐ No	Comment:
39	Contact Persons for Participants ☐ Yes ☐ No	Comment:

C. Enablers & other issues

39	Are Qualification and experiences of the Participating Investigators appropriate? ☐ Yes ☐ No	Comment:
40	Involvement of local researchers and institution in the protocol design, analysis and publication of results ☐ Yes ☐ No	Comment:
41	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate	Comment:
42	Contribution to Development of Local Capacity for Research and Treatment ☐ Yes ☐ No	Comment:
43	If more than one institution executes the project, Memorandum of Understanding attached? ☐ Yes ☐ No	Comment:
44	Are human blood/tissue or other biological materials exported abroad? ☐ Yes ☐ No ☐ Not applicable	Comment:
45	If biological material exported abroad, Material Transfer Agreement attached? ☐ Yes ☐ No	Comment:
46	Disclosure or Declaration of Potential Conflicts of Interest ☐ Declared ☐ Not Declared	Comment:
47	Are there any issues that are not clear &need clarification from the principal investigator? ☐ Yes ☐ No	List issues that need more clarification:

Annex 2:Assessment Report
(EPHI-IRB AF 02-008/02.0)

Review Date (DD/MM/YYYY):……

Protocol number: EPHI-IRB-☐☐☐-☐☐☐☐

Protocol Title :		
Elements Reviewed (EPHI-IRB F 01-008)	☐ Attached ☐ Not attached	
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
Decision :	☐ Approved ☐ Approved with minor changes ☐ Resubmission ☐ Disapproved	
Comment:		
Reviewer's Signature :		Date:

Annex 3:IRBDecision Form
(EPHI-IRB AF 03-008/02.0)

Meeting No.: MMM-DD-MM-YYYY Date: (DD/MM/YYYY)

Protocol number:EPHI-IRB-☐☐☐-☐☐☐☐

Protocol Title :		
Principal Investigators:		
Institute:		
Elements Reviewed (EPHI-IRB AF01-008/02.0) :	☐ Attached	☐ Not attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
Mode of Review	☐ Expedited Review	☐ Full Board Review
Additional Remarks, if any		
Decision of the meeting:	☐ Approved ☐Approved with Recommendation ☐ Resubmission ☐ Disapproved	

EPHI-IRB Secretary

Name &Signature:……Date:…….

EPHI-IRB Chairperson

Name &Signature Signature:……Date:…….

Annex4: Notification Form
(EPHI-IRB AF 04-008/02.0)

Protocol number: EPHI-IRB-☐☐☐-☐☐☐☐

Protocol Title :	
Principal Investigators:	
Institute:	
Study site/s	
Points to be addressed for resubmission or approval with minor comments	
IRB Secretariat _____	Signature _____ Date:_____

Annex 5: Certificate of Approval
(EPHI-IRB AF 05-008/02.0)

Protocol number……EPHI-IRB-☐☐☐-☐☐☐☐
Minutes No.: MMM-DD-MM-YYYY

Protocol Title :	
Investigators:	
Institute:	
Study site/s	
Elements Reviewed (EPHI-IRB AF 01-008/02.0):	☐ Attached ☐ Not attached
Mode of Review	☐ Expedited ☐ Full Board
Decision of the meeting	☐ Approved

I. Elements approved: 1. Protocol Version No.: ……

2. Protocol Version Date: ……..….

3. ICF Version No.: ……

4. ICF Version Date: ……..……

II. . Obligations of the PI:

1. Should comply with the standard international &national scientific and ethical guidelines
2. All amendments and changes made in protocol and consent form needs IRB approval
3. The PI should report SAEwithin 48 hours of the event
4. This approval certificate is valid for only one year (specified bellow). The PI should submit continuation request before expire dateof approval, if projects is to continue
5. Final report/Thesis and Manuscripts should be submittedto the IRB secretariatafter completion of the study

Institutional Review Board Approval Date:_____
ApprovalPeriod: From_____ to_____
Follow up report expected in:
6 months ____ 9 months_____one year____

EPHI-IRB Chairperson
Name &Signature _____
Date:_____

EPHI Director General
Name &Signature _____
Date:_____

Annex 6:Disapproval notification form
(EPHI-IRB AF 06-008/02.0)

Protocol number: EPHI-IRB-☐☐☐-☐☐☐☐
Minutes No.: MMM-DD-MM-YYYY

Protocol Title :	
Principal Investigators:	
Institute:	
Study site/s	
Reasons for disapproval	
Chairperson, IRB	Signature _____ Date:_____

Annex 7: Disapproval complaint application form
(EPHI-IRB AF 07-008/02.0)

Protocol number: EPHI-IRB-☐☐☐-☐☐☐☐

Protocol Title :	
Principal Investigators:	
Institute:	
Study site/s	
Reasons for complaint	
Applicant	Signature _____ Date:_____

Annex 8: Final Document Submission Verification Form
(EPHI-IRB AF 08-008/02.0)

Protocol Title: _____

Principal Investigator: _____

Protocol Number: _____

Meeting minutes in which protocol was discussed (cite all minutes if protocol continues to be discussed in more than one meeting): _____

I,secretary of EPHI-IRB or administrative staff of SERO have auditedthe final submitted document of the aforementioned protocol; which is prepared as per full board or chairperson's recommendation, suggestion and decision; for signature on approval/disapproval certificate by the chairperson of EPHI-IRB and Director General of EPHI. I certify that the following relevant issues are addressed; documents are submitted and properly documented:

1. Recommendations and suggestions made during the board meeting(s) on the protocol are fully addressed in the final submitted protocol and submitted

   Yes ☐ No ☐

2. Recommendations and suggestions made during the board meeting on the informed consent form, given study protocol involves human study participantsand/or animals, are fully addressed in the final submitted protocol and submitted

   Yes ☐ No ☐

3. Informed consent form and study protocols that are prepared in English and translated to local languages by the investigators or based on IRB recommendations are submitted as part of the project document

   Yes ☐ No ☐ Not relevant ☐

4. Completed assessment forms by two reviewers, compiled comments to investigators, and point by point response of investigators to the comments are attached

   Yes ☐ No ☐

5. MTA and/or MoU is/are attached as per relevant EPHI-IRB SOP

   Yes ☐ No ☐

6. Information on the covering/first page of the protocol is complete and adheres with the latest protocol writing format of EPHI-IRB

   Yes ☐ No ☐

7. Commencement for execution of the project (including training) is planned following approval of the protocol (check implementation plan; respective IRB minutes or decision by chairperson for expedited review)

   Yes ☐ No ☐

8. Appropriate version number and date are specified as footnote in the protocol, ICF and data collection instruments

   Yes ☐ No ☐

9. The principal investigator and co-investigator(s) have signed on their respective roles and responsibilities section of the protocol

   Yes ☐ No ☐

10. Separate letter(s) requesting waiver of informed consent and/or assent is/are attached, given that IRB accepts the request

    Yes ☐ No ☐

11. Complete curriculum vitae of the principal investigator and one page summary of all co-investigators is attached

    Yes ☐ No ☐

12. Research Ethics and/or GCP training certificate is attached

    Yes ☐ No ☐

Nameof secretary/administrative staff: ……

Signature: ……

Date of submission for signature by IRB chairperson: ……..