
 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 1 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Table of Contents

No.	Content	Page No.
1.	PURPOSE	2
2.	SCOPE	2
3.	RESPONSIBILITY	2
4.	FLOW CHART	2
5.	DETAILED INSTRUCTIONS	3
5.1.	BEFORE EACH BOARD MEETING	3
5.1.1.	Check for filled up forms (form number) for completeness.	3
5.1.2.	Consider the appropriate review channel of each protocol	3
5.1.3.	Assign protocol reviewers	3
5.1.4.	Prepare meeting agenda	3
5.1.5.	Distribution of Protocol to the IRB before the meeting	4
5.1.6.	Prepare for the meeting	4
5.2.	DURING THE MEETING	5
5.3.	VOTING	5
5.4.	AFTER THE BOARD MEETING	6
5.5.	PREPARING THE MINUTES AND THE DECISION FORMS	6
5.5.1.	Assembling the meeting minutes and the decision form	6
5.5.2.	Contents of the IRB Meeting Minutes	6
5.5.3.	Approval of the minutes and the decision	7
5.5.4.	Filing the minutes	7
5.5.5.	Distributing the minutes and the decision	8
6.	GLOSSARY	8
7.	REFERENCES	8
8.	ANNEX	8
	ANNEX 1: MEETING AGENDA FORMAT OF EPHI-IRB	9
	ANNEX 2: MEETING MINUTES OF EPHI-IRB	11
	ANNEX 3: CONFLICT OF INTEREST FORM TO BE SIGNED BY IRB MEMBER BEFORE BOARD MEETING	23

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 2 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

1. Purpose

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of EPHI-IRB meetings.

2. Scope


This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all IRB meetings.

3. Responsibility

It is the responsibility of the Secretariat of IRB to prepare the agenda for the meeting and to ensure the quality and validity of the minutes after the meeting is over. The secretary will present the agendas to the board and will record the minute of the meeting. The Chairperson should review and approve the agenda and the minutes. In addition, the chair-person leads the IRB meeting.

4. Flow chart

No.	Activity	Responsibility
1	Agenda setting ↓	IRB Secretariat/IRB
2	Conducting meeting and minute taking ↓	Chairperson/IRB Secretariat/IRB
3	Voting ↓	IRB Members without conflict of interest/ Chairperson
4	Minute circulation ↓	IRB Secretariat / Chairperson
5	Minute approval and communication	IRB Secretariat/IRB/Chairperson

 <p>www.ephi.gov.et</p>	<p>Ethiopian Public Health Institute Institutional Review Board (IRB)</p>	<p>EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 3 of 23</p>
	<p>8.1. Agenda Preparation, Meeting and Minutes Taking Procedures</p>	

5. Detailed instructions

5.1. Before each Board meeting

5.1.1. Check for filled up forms (form number) for completeness.

- An administrative staff member /officer:
 - Reviews the new study application for completeness.
 - Documents the review by completing the appropriate checklist (form number). If incomplete, the IRB officer attempts to obtain the information from the person who submitted the application package.

5.1.2 Consider the appropriate review channel of each protocol


- Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel
 - EPHI-IRBSOP/010/02.0 for Expedited Review
 - EPHI-IRBSOP 011/02.0 for Initial Review of Submitted Protocols
 - EPHI-IRBSOP/013/02.0 for Review of Resubmitted Protocols
 - EPHI-IRBSOP/014/02.0 for Review of Protocol Amendments
 - EPHI-IRBSOP/015/02.0 for Continuing Review of Study Protocols
 - EPHI-IRBSOP/019/02.0 for Review of Protocol Terminations
 - EPHI-IRBSOP/016/02.0 for Review of Final Reports

5.1.3 Assign protocol reviewers

- Assign at least two reviewers (for technical and ethical reviews) for initial review of each submitted protocol by the IRB Secretariat.
 - *The technical reviewer prepares a brief protocol summary, including a statement of the purposes, the evaluation parameters, and the methodology of the protocol. The ethical reviewer examines the consent form for completeness of information and protection of human subjects*
 - The assignment should be based on the information provided in EPHI-IRB SOP/005/02.0 and EPHI-IRB SOP/006/02.0.

5.1.4 Prepare meeting agenda

- Schedule the review meeting as soon as possible after the receipt of either at the time of the next scheduled meeting or *within 2 weeks after submission*
- Consult the Chairperson to schedule the meeting date.
- Prepare the meeting agenda, according to the format shown in Annex 1 (EPHI-IRB AF 01-022/02.0). The format can be

 <p>www.ephi.gov.et</p>	<p>Ethiopian Public Health Institute Institutional Review Board (IRB)</p>	<p>EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 4 of 23</p>
	<p>8.1. Agenda Preparation, Meeting and Minutes Taking Procedures</p>	

subjected to conditional modification when there is a need to close pending issues, discuss on issues that need immediate decision and further action, etc. during the specific meeting


- Schedule protocols in the agenda on a first-come first-serve basis.
- Include “request to appeal” items in the agenda, upon receipt of the correspondence, preferably during the next convened Board meeting
- Prepare invitation letters /email/ oral communication/phone call to the reviewers and the IRB members
 - Allow at least three weeks for the review process
- Specify the due date for the return of comments
- Include a protocol assessment form EPHI-IRB AF 01-008/02.0 with the protocol package along with the invitation letter, a response form for selected reviewer
- Write down the running number of the protocol in the square boxes at the bottom right corner of the form EPHI-IRB AF 01-008/02.0
- Sign the second page of the form EPHI-IRB AF 01-008/02.0.
- Prepare the package for delivery
- Record the name of the assigned reviewers in the appropriate database or the review assignment file

5.1.5 Distribution of Protocol to the IRB before the meeting

- Keep in mind Procedure for Maintaining Confidentiality of IRB documents (EPHI-IRB SOP/027/02.0) when preparing and distributing documents
- Distribute copies of the protocol submission packages to the assigned reviewers and IRB members by either electronic mail (if electronic submission protocols) by post *two weeks in advance of the scheduled meeting*
- Keep copies of “sent” e-mail, cover memos and/or letters accompanying posted materials in the Correspondence section of the respective protocol file
- Verify (verbally, by e-mail or post) with the members whether the protocol packages are received

5.1.6 Prepare for the meeting

- Make a room reservation on the schedule meeting date and time.

 <p>www.ephi.gov.et</p>	<p>Ethiopian Public Health Institute Institutional Review Board (IRB)</p>	<p>EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 5 of 23</p>
	<p>8.1. Agenda Preparation, Meeting and Minutes Taking Procedures</p>	


- Make sure that the room, equipment and facilities are available in good running condition and cleaned for the meeting day.

5.2. During the meeting

- The IRB may allow investigators, project managers, sponsors, etc., to attend the portion of the Board meeting related to their studies.
- At the discretion of the Chairman, guests may be allowed to observe the Board meetings.
- These guests may include a potential client, students, etc.
- Guests are required to sign a confidentiality agreement (EPHI-IRB AF 02-004/02.0).
- The Secretariat reports on the minutes of the previous meeting and presents the agenda for discussion.
- The Secretariat records the discussions and the decisions made during the meeting.
- The Chairperson may inform members and attendees of the rules being followed during meetings.
- The meeting proceeds in the order organized in the agenda; however, the Chairperson may allow some switching depending on the situation.
- The approval process starts when one of the reviewers gives a brief about the study and presents his/her observations and comments.
- In case the reviewer cannot be present during the meeting, a member of the Secretariat or an IRB member may give the briefing about the study by reading the comments and evaluation of the reviewers.
- The other members give their comments right after the presentation and the discussion about the study takes place.
- Investigators may be allowed to present their projects in brief and clarify any questions the IRB members may have.

5.3. Voting

- In order to avoid conflict of interest, only those Board members who are independent of the investigator and the sponsor of the trial will vote on the research-related matters.
- All voting will take place after the observers / presenters / board members with a conflict of interest leave the meeting room.
- The Chair determines if the number of voting Board members is sufficient to constitute a quorum and proceeds accordingly.
- A Board member makes a motion to recommend action on a protocol or issue being discussed.
- The motion is seconded and voting takes place.

 <p>www.ephi.gov.et</p>	<p>Ethiopian Public Health Institute Institutional Review Board (IRB)</p>	<p>EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 6 of 23</p>
	<p>8.1. Agenda Preparation, Meeting and Minutes Taking Procedures</p>	

- A motion is carried out once the majority of IRB members vote in favor of the motion.

5.4. After the Board meeting

- As soon as possible after each meeting, a copy of the minutes is sent to a senior administrative staff member for quality control and review
- The senior administrative staff member indicates review by signing and dating the minutes
- Following staff review, the minutes are given to the Chairperson or designee for review and approval
- The Chairperson indicates approval by signing and dating the minutes
- A member of the administrative staff maintains the official copies of the minutes in accordance with departmental archiving procedures


5.5. Preparing the Minutes and the Decision Forms

5.5.1 Assembling the meeting minutes and the decision form

- Use the format as shown in Annex 2 (EPHI-IRB AF 02-022/02.0) to write a minute
- Compose the summary of each meeting discussion and decision in a concise and easy-to-read style
- Make sure to cover all contents in each particular category
- Check spelling, grammar and context of the written minutes
- Finish the minutes within a week after the meeting

5.5.2 Contents of the IRB Meeting Minutes

- The official minutes of the Board meeting consist of, but are not limited to, the following:
 - Name of person preparing the minutes
 - Location where the meeting was held (city, state)
 - Meeting date
 - Attending board members and guests
 - Agenda items
 - Individual serving as Chairperson of the meeting
 - Determination of a duly constituted quorum by the Chairperson to proceed with the meeting
- Requirements for each study or activity requesting Approval:
 - Sponsor's name
 - Protocol number/date/version of protocol, when available;
 - Investigator's name
 - Advertisements

 <p>www.ephi.gov.et</p>	<p>Ethiopian Public Health Institute Institutional Review Board (IRB)</p>	<p>EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 7 of 23</p>
	<p>8.1. Agenda Preparation, Meeting and Minutes Taking Procedures</p>	


- Name of board member presenting study materials
- Discussion as deemed appropriate by the Chairperson
- Number of members voting ‘yes’, ‘no’, or ‘abstention’
- Number of abstentions and the reason for the abstention
- Reference to the investigator approval letter that lists all changes requested by the board
- Determination of the next requested continuing review
- Requirements for each study or activity requesting Expedited Review:
 - Sponsor’s name
 - Protocol number, if applicable
 - Investigator’s name
 - Lists of expedited approval requests and outcomes
- Required for each Continuing Review Report:
 - Sponsor’s name
 - Protocol number, if applicable
 - Investigator’s name
 - Indication of the Board’s determination to continue, terminate, or amend the study
 - Lists of recommendations or actions to be taken up with the investigator, if applicable
- Required for each Adverse Event notification and Final Report:
 - Sponsor’s name
 - Protocol number, if applicable
 - Investigator’s name
 - Actions deemed appropriate by the Board’s review
- Required for Termination of Approval:
 - Sponsor name’s
 - Protocol number, if applicable
 - Investigator’s name; reason for termination

5.5.3 Approval of the minutes and the decision

- Check the correctness and completeness of the minutes
- Get the Chairperson of the IRB to sign and date the relevant sections of the minutes of the IRB meeting and the decision form

5.5.4 Filing the minutes

- Place the original version of the minutes and the signed decision form in the IRB files for the specific protocol.
- Place all correspondence in the appropriate file.

 <p>www.ephi.gov.et</p>	<p>Ethiopian Public Health Institute Institutional Review Board (IRB)</p>	<p>EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 8 of 23</p>
	<p>8.1. Agenda Preparation, Meeting and Minutes Taking Procedures</p>	

- Place a copy of the approval letter in the “minutes” file to inform the Board Members of the Expedited approval.
- Document the appeal requests in the meeting minutes.

5.5.5 Distributing the minutes and the decision

- Send a copy of the relevant sections of the minutes and the decision form to the applicants for their records by mail or other means
- Send the approved minutes to the IRB members
- Send the decision of the IRB for an appeal request to the person concerned in writing
- Record the receivers and the delivery date


6. Glossary

Agenda	A list of things to be done; a program of business at a meeting
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Quorum	Number of IRB members required to act on any motion presented to the Board for action.
Majority vote	A motion is carried out if one half plus one member of the required quorum votes in its favor.

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. Associated EPHI-IRB SOP/004/02.0,008/02.0,009-015/02.0, 024/02.0, and 027/02.0.

8. Annex

 www.eph.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 9 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Annex 1: Meeting Agenda Format of EPHI-IRB
(EPHI-IRB AF 01-022/02.0)

Meeting no.:		Meeting date:	
<input type="checkbox"/> Ordinary Meeting		<input type="checkbox"/> Emergency meeting	
Location where the meeting is held (city, state)		Ethiopian Public Health Institute, Addis Ababa, Ethiopia	
Agenda items:	Attached		
Starting time:		Adjourned time :	

Attending board members and guests:

- | | |
|----|-----|
| 1. | 8. |
| 2. | 9. |
| 3. | 10. |
| 4. | 11. |
| 5. | 12. |
| 6. | 13. |
| 7. | 14. |

Individual serving as Chairman of the meeting: _____

Determination of a dully constituted quorum by the Chairperson to proceed with the meeting.

Prepared by _____
Staff, Secretariat Office

Reviewed and Approved by _____


Chairperson, IRB

Secretary, IRB

Signature


Signature
Date: _____

Date: _____

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 10 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Agenda of the IRB Ordinary Meeting

1. Approval of Agenda
2. Declaration of Conflict of interest (COI)
3. Approval of the last meeting: IRB Minutes No. _____
4. Matters arising from the minutes of the last meeting
5. Protocol Presentations, Review, Discussion and Voting
 - 4.1. Protocol for Initial Review
 - 4.2. Resubmitted Protocol
 - 4.3. Protocol on Amendment
 - 4.4. Pending Protocols
 - 4.5. SAE Report
 - 4.6. Expedited review
6. Issues to be informed to the members
7. Issues to be reported for consideration
8. Other issues of interest to the members

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 11 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Annex 2: Meeting Minutes of EPHI-IRB
(EPHI-IRB AF 02-022/02.0)

Regular/Emergency Meeting

Venue:.....

Date: dd/mm/yyyy

Time:

Attendance

Present

- Member 1
- Member 2
- Member 3
- Member 4
- Member 5
- Member 6
- Member 7

Absent

- Member 1
- Member 2

Excused

- Member 1
- Member 2

Others

- Staff
- Guest


1. Call to Order

<Title, First Name, Surname>, Chair, called this meeting to order at <time>.

2. Determination of Quorum

Quorum was declared with the presence of <number> members, inclusive of the presence of <number> non-institutional, <number> non-medical/lay, and <number> female members, as confirmed by the Member Secretary, <Title, Name, Surname>.

3. Disclosure of Conflict of Interest

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 12 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

<Title, Surname of Chair>, called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting. The following member/s inhibited from participation in the deliberations during the full board meeting for the following reasons:

<Title, Name, Surname> as Principal Investigator **for the study entitled, “TITLE” (PROTOCOL NUMBER) EPHI-IRB AF 03-028/01.0**

4. Approval of the Agenda

<Title, Surname of Chair>presided over the discussion of the agenda of the meeting for <dd/mm/yyyy> (**Date of current meeting**). The agenda was corrected during the discussion and approved as amended.

5. Approval of the Minutes of the Last Meeting

5.1. Corrections in the Meeting Minutes

5.2. Approval of the Meeting Minutes


5.3. Matters Arising from the Minutes of the Last Meeting requiring EC action

6. Protocol Review

6.1. Full Board Review of Protocols

6.1.1. Protocols for Initial Review (Full Board Review)


Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 13 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Assessment of Scientific Issues	<ol style="list-style-type: none"> 1. Rationale and literature review 2. Objectives/Expected output 3. Research/Study design 4. Sampling design and sample size 5. Control arms (placebo or less effective intervention, if any) 6. Inclusion criteria 7. Exclusion criteria 8. Withdrawal criteria 9. Statistical and data analysis plan 10. PI qualification and COI 11. Suitability and choice of site 12. Research instruments and tools
Assessment of Ethical Issues	<ol style="list-style-type: none"> 1. Vulnerability 2. Risks and benefits 3. Insurance and medical care 4. Compensation and reimbursement 5. Privacy and confidentiality 6. Informed consent process 7. Completeness of patient information sheet (PIS) and informed consent form (ICF) 8. Language and translation of PIS and ICF 9. Voluntariness 10. Assent and parental consent
Conclusion and Recommendations	
Action Taken	Decision (Approve <date of continuing review>; Minor Modification, which can be expedited at the level of the Member Secretary; Major Modification, which requires resubmission and full board review; Disapprove)
Approval Expiration Date (if applicable)	
Frequency of Continuing Review (in case of approval)	
Other Comments (if applicable)	

6.1.2. Protocols for Modification or Resubmissions (Full Board Review)


Protocol Code	
Protocol Resubmission Date	<dd/mm/yyyy>
Protocol Title	

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 14 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	
<i>Assessment of PI Response to Initial Review</i>	
Conclusion and Recommendations	
Action Taken	Decision (Approve <date of continuing review>; Minor Modification, which can be expedited at the level of the Member Secretary; Major Modification, which requires resubmission and full board review; Disapprove)
Approval Expiration Date (if applicable)	
Frequency of Continuing Review (in case of approval)	
Other Comments (if applicable)	

6.1.3. Amendments (Full Board Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	
<i>Assessment of Amendment</i>	
Conclusion and Recommendations	
Action Taken	Decision (Approve; Minor modification to the amendm reasons for action, subject to expedited review at the lev Member Secretary; Major modification to the amendme reasons for action, subject to full board review; Disappr

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 15 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	


Other Comments (if applicable)	
--------------------------------	--

6.1.4. Protocol Non-Compliance (Deviation or Violation) Reports (Full Board Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	
<i>Assessment of Protocol Non-Compliance Report</i>	
Conclusion and Recommendations	
Action Taken	Decision (No further action required; Request information; Recommend further action)
Other Comments (if applicable)	

6.1.5. SAE Reports (Full Board Review)

Protocol Code		
Protocol Approval Date	<dd/mm/yyyy>	
Report Date	<dd/mm/yyyy>	
Protocol Title		
Principal Investigator		
Primary Reviewers		
Sponsor/CRO		
Quorum Status		
Conflict of Interest		
<i>Assessment of SAE Report</i>		
SAE Details	Submission Date	<dd/mm/yyyy>
	Date of SAE	<dd/mm/yyyy>
	Onsite or offsite	
	Country (if offsite)	

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 16 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	


	SUSAR or Non-SUSAR	
	Related or Non-Related to the Study	
	Nature of SAE	
	Status	
Conclusion and Recommendations		
Action Taken	Decision (No further action required; Request information; Recommend further action)	
Other Comments (if applicable)		

6.1.6. Requests, Queries, and Complaints (Full Board Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	
Assessment of Request, Query or Complaint	
Conclusion and Recommendations	
Action Taken	Decision (No further action required; Request information; Recommend further action)
Other Comments (if applicable)	

6.1.7. Site Visit Reports (Full Board Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 17 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	


Quorum Status	
Conflict of Interest	
<i>Assessment of Site Visit Report</i>	
Conclusion and Recommendations	
Action Taken	Decision (No further action required; Request information; Recommend further action)
Other Comments (if applicable)	

6.1.8. Study Termination (Full Board Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	
<i>Assessment of Risks from Study Termination</i>	
Conclusion and Recommendations	
Action Taken	Decision (Approve; Request information; Recommend action)
Other Comments (if applicable)	

6.1.9. Continuing and Progress Reports (Full Board Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	
<i>Assessment of</i>	

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 18 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

<i>Continuing and Progress Report</i>	
Conclusion and Recommendations	
Action Taken	Decision (Approve; Request information; Recommend further action)
Other Comments (if applicable)	


6.1.10. Final Reports (Full Board Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Quorum Status	
Conflict of Interest	
<i>Assessment of Final Report</i>	
Conclusion and Recommendations	
Action Taken	Decision (Approve; Request information; Recommend action)
Other Comments (if applicable)	

6.2. REPORT OF PROTOCOLS EXEMPT FROM REVIEW AND EXPEDITED REVIEW PROTOCOLS, REVISED PROTOCOLS, AND POST-APPROVAL REPORTS SUBMITTED FOR EXPEDITED REVIEW

6.2.1. Protocols Exempt from Review

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Protocol Approval Date	<dd/mm/yyyy>

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 19 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

6.2.2. Protocols for Initial Review (Expedited Review)

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (Approve <date of continuing review>; Minor Modification, which can be expedited at the level of the Member Secretary; Major Modification, which requires resubmission and full board review; Disapprove)


6.2.3. Protocols for Modification or Resubmissions (Expedited Review)

Protocol Code	
Protocol Submission Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (Approve <date of continuing review>; Minor Modification, which can be expedited at the level of the Member Secretary; Major Modification, which requires resubmission and full board review; Disapprove)

6.2.4. Amendments (Expedited Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Date of Amendment Submission	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (Approve; Minor modification to the amendm citing reasons for action, subject to expedited review at of the Member Secretary; Major modification to the amendment, stating reasons for action, subject to full bc review; Disapprove)

6.2.5. Protocol Non-Compliance (Deviation or Violation) Reports (Expedited Review)

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 20 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (No further action required; Request information, Recommend further action)

6.2.6. SAE Reports (Expedited Review)


Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (No further action required; Request informati Recommend further action)

6.2.7. Requests, Queries, and Complaints (Expedited Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (No further action required; Request informati Recommend further action)

6.2.8. Site Visit Reports (Expedited Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (No further action required; Request informati

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 21 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

	Recommend further action)
--	---------------------------

6.2.9. Study Termination (Expedited Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (Approve; Request information; Recommend action)


6.2.10. Continuing and Progress Reports (Expedited Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (Approve; Request information; Recommend action)

6.2.11. Final Reports (Expedited Review)

Protocol Code	
Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Protocol Title	
Principal Investigator	
Primary Reviewers	
Sponsor/CRO	
Action Taken	Decision (Approve; Request information; Recommend action)


7. OTHER MATTERS

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 22 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

8. ADJOURNMENT

This meeting was adjourned at<time>.

Prepared by: _____ DATE: _____ <dd/mm/yyyy>	<u>Signature over <Title, Name, Surname></u> SECRETARIAT STAFF
Checked by: _____ DATE: _____ <dd/mm/yyyy>	<u>Signature over <Title, Name, Surname></u> MEMBER SECRETARY
Approved by: _____ DATE: _____ <dd/mm/yyyy>	<u>Signature over <Title, Name, Surname></u> CHAIR (in behalf of the EC)

 www.ephi.gov.et	Ethiopian Public Health Institute Institutional Review Board (IRB)	EPHI-IRB SOP/022/02.0 Effective Date: 30August 2019 Page 23 of 23
	8.1. Agenda Preparation, Meeting and Minutes Taking Procedures	

Annex 3: Conflict of Interest Form to be Signed by IRB Member Before Board Meeting
(EPHI-IRB AF 03-022/01.0)

Date (dd/mm/yyyy):
 To -----
 The Chairperson, IRB

I hereby declare the conflict of interest for the protocol no. -----
 entitled, _____

- as :
1. I am the investigator / co-investigator/Author/study team
 2. I have Financial interest
 3. _____
 4. _____

in the project which will be discussed in today's meeting i.e.dd day of mm month
 yyyy year.

MR/MRS/MS/Dr. _____
 Member, IRB

 Chairperson, IRB