3.1. Management of Protocol Submission

Table of Contents

1. Purpose

This standard operating procedure is designed to describe how the Secretariat of the Institutional Review Board(IRB) manages protocol submissions to the EPHI-IRB.

2. Scope

Protocol submissions include:

- Submission for Initial Review
- Resubmission of Protocols with Corrections
- Protocol Amendment
- Continuing Review of Approved Protocols
- Final Report Review
- Protocol Termination

3. Responsibility

It is the responsibility of the IRB secretariat to receive, record, distribute for review and get the submission packages approved by the IRB, as well as to deliver the review results to the protocol applicants.

4. Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages	IRB Secretariat
	↓	
2	Check for submission items and completeness	IRB Secretariat
	↓	
3	Process submitted package	IRB Secretariat
	↓	
4	Documentation	IRB Secretariat

5. Detailed instructions

5.1.Receive submitted packages

5.1.1 Initial Review Application

- Go to 5.2.

5.1.2. Resubmission of Protocols with Corrections

- Retrieve the previous receipt form from the Secretariat's records, and
- Go to step 5.2.1.2

5.1.3 Protocol Amendment

- Retrieve the previous receipt form from the Secretariat's records, and
- Go to step 5.2.1.3

5.1.4 Continuing Review of Approved Protocols

- Retrieve the previous receipt form from the Secretariat's records, and
- Go to step 5.2.1.4

5.1.5 Final Report Review

- Retrieve the previous receipt form from the Secretariat's records, and
- Go to step 5.2.1.5

5.1.6 Protocol Termination

- Retrieve the previous receipt form from the Secretariat's records, and
- Go to step 5.2.1.6

5.2. Check for submission items

5.2.1.Get relevant forms

5.2.1.1Initial Review Application

- A checklist for contents of a submitted package, form EPHI-IRB AF 01-007/02.0
- A document receipt form, EPHI-IRB AF 05-007/02.0 and an application form for initial review, EPHI-IRB AF01-011/02.0
- Go to step 5.2.2
- For **e-submission**, go to 5.2.3 (Filled EPHI-IRB AF 01-010/02.0application form for initial review should be attached)

5.2.1.2 Resubmission of Protocols with corrections

- A checklist form (EPHI-IRB AF 01-007/02.0)
- A document receipt form (EPHI-IRB AF 05-007/02.0)
- A review of resubmitted protocol form (EPHI-IRB AF 01-013/02.0)

- Go to step 5.2.2

5.2.1.3 Protocol Amendments

- A checklist for contents of a submitted package, form EPHI-IRB AF 01-007/02.0
- A document receipt form, EPHI-IRB AF 04-007/02.0
- Go to step 5.2.2

5.2.1.4 Continuing Reviews of Approved Protocols

- A checklist for contents of a submitted package, form EPHI-IRB AF 01-007/02.0
- A document receipt form, EPHI-IRB AF 05-007/02.0
- A re-review report form, EPHI-IRB AF 01-011/02.0
- Go to step 5.2.2

5.2.1.5 Final Report Review

- A checklist for contents of a submitted package, form EPHI-IRB AF 01-007/02.0
- A document receipt form, EPHI-IRB AF 05-007/02.0
- Go to step 5.2.2

5.2.1.6Protocol Termination

- A checklist for contents of a submitted package, form EPHI-IRB AF 01-007/02.0,
- A document receipt form, EPHI-IRB AF 05-007/02.0,and
- Go to step 5.2.2

5.2.2 Fill in the forms:

- Give the form EPHI-IRB AF 01-007/02.0,document receipt form EPHI-IRB AF 05-007/02.0 and the form EPHI-IRB AF 01-011/02.0to the applicants to fill up the relevant information.

5.2.3 Verify Contents of Submitted Package

- Use the checklist for contents of a submitted package, form EPHI-IRB AF 01-007/02.0,
- Check the applicable documents to ensure that all required forms and materials are contained within the submitted package
- Verify contents of the protocol submitted package to include:
  - Original Application Form for Initial Review
  - Summary Sheet or Memorandum of the study Protocol
  - Study Protocol and Related Documents
  - Supporting letterfrom EPHI Directors, Deputy Director Generals, Director General and other institutes to EPHI-IRB
  - Memorandum of Understanding MoU) if project is to be executed by two or more institutions (Use SOP Template included under AnnexEPHI-IRB AF 02-007/02.0). Protocols submitted from Ministry of Health and its agencies as well asstudents are not subjected to be supported by MoU, rather, supporting letter from the respective office or university suffice to continue the review process
  - Material Transfer Agreement (MTA) between provider and recipient institutions if any biological material is to be exported outside Ethiopia (Use Annex EPHI-IRB AF 03-007/02.0as template) and analyzed. Biological materials to be exported and analyzed by project investigators in a laboratory abroad due to limited institutional capacity and/or improve efficiency without involving any other party or individual may however be exempted from MTA throughdecision to be made by full board meeting.Supporting relevant document(s)and commitment letter from the PI or designeefor takingfull accountability of

ensuring the aforementioned process,highest possible measure to maintain confidentiality of data,standard disposal or returning of all leftover of exported biological samples or its productshould however be attached given IRB permits export without MTA.

- Receive Director General/Deputy Director General/Directorate Director supporting letter for submission of the protocol (EPHI-IRB AF 04-007/02.0) for review and determination
- Check completeness of necessary information in the Application Form for Initial Review
- Check the Summary Sheet or Memorandum of the study protocol for inclusion of the followings:
  - Title of the Protocol
  - Principal Investigator
  - Sponsor
  - Summary
  - Type of Protocol (screening, survey, pre-clinicallaboratory-based studies)
  - Objectives
  - Anticipated Outcome
  - Inclusion/Exclusion Criteria
  - Withdrawal or discontinuation Criteria
  - Modes of Treatment Studied
  - Methodology (synopsis of study design)
  - Analysis (methods)
  - Activity plan / Timeline
  - IND Number (if applicable)
  - Schedule and Duration of Treatment
  - Efficacyor Evaluation Criteria (Response/Outcome)

- Safety Parameters Criteria (Toxicity)
- Conflict of Interest Declaration

- Check the submitted **Protocol and Related Documents** for the following contents
  - Participants' information sheets
  - Informed Consent Form
  - Case Record Form (CRF) for clinical trial studies
  - Study budget and budget justification
  - Curriculum Vitae (CV) of investigators
  - Other pertinent documents to the specific protocol as appropriate
  - GCP training certificate and/or basic research ethics trainingcertificate
  - MoU, if the study is to be conducted with collaborating institutes
- See if changes made to the documents be underlined or highlighted

5.2.4 Verify electronic documents (where applicable)

- Place the electronic computer documents (protocol summary, protocol and protocol-related documents) on the IRB server or the Local Area Network at the time of submission for initial protocol review or protocol amendment packages in the following drive and folder:

  C:\studies\protocols\new\ (short name of title)
- Verify that the electronic version and the contents of the documents match the copy submitted by comparing a hard copy of the electronic document with the submitted one
- Print out the protocol documents

- Verify the correctness of the documents
- Check that all pages of the documents have been included and that the submitted protocol and protocol-related documents do not have missing pages
- Certify the printed hard copy in the same manner as the submitted document(s) with the dated signature
- Stamp and assign a running number to the received protocols, applying the system of 7 letters and 7 digits indication institutional review board of EPHI followed by hyphen then sequence of protocol number and year of submission. For example**EPHI-IRB-188-2019** means **EPHI-IRB:** Institutional Review Board of Ethiopian Public Health institute;**189**: protocol number, **2019**: year of submission that is submitted in 2019
- Count for correct numbers of copies
- Store the hard copy of the electronic document with the submitted documents
- Use the assigned running number of the protocol as the labeled name
- Identify clearly as the hard copy of the electronic document, and
- Return incomplete submission package to the protocol applicant with notification of missing items

5.2.5Create a Protocol Specific File

- Get the "**Protocol Submission"** file
- Record the name and the number of the submitted protocol
- Record the receiving date and the name of the receiver

5.3. Process submitted package

- Get the Form EPHI-IRB AF 01-007/02.0, document receipt form EPHI-IRB AF 05-007/02.0 and EPHI-IRB AF 01-011/02.0back from the applicants
- Check for completeness of information
- Notify the applicants if a package is incomplete
- State clearly the items missing in the package
- Fill up the related parts and the missing documents
- Stamp the receiving date on the letter and the first page of the documents
- Initial the receiver's name on the receiving documents,
- Make a photocopy of the completed Form EPHI-IRBAF 05-007/02.0
- Return the original copy of EPHI-IRB AF 05-007/02.0to the applicants for their records
- Attach the filled checklist (EPHI-IRB AF 01-007/02.0),supporting letter from respective official (EPHI-IRB AF 04-007/02.0) and form EPHI-IRB AF 05-007/02.0; as well as copy/copies of MoU (EPHI-IRB AF 02-007/02.0.) and MTA (EPHI-IRB AF 03-007/02.0.), if there is/are anywith a staple
- Keep copy of the document receipt form in the "Protocol submission file"
- Attach an Initial Review Application Form (EPHI-IRB AF 01-011/02.0) to the Research Protocol packages, and
- Keep the copy of the submitted documents with original signatures in the "Submission" file.

5.4.Documentation of received packages

- Bind the packages together appropriately, and

- The submitted hard copy protocols and related documents will be labeled and stored in the locked shelf of SERO in FIFO sequence.

6. Glossary

FIFO	First in First Out sequence
GCP	Good Clinical Practice
MTA	Material Transfer Agreement
MoU	Memorandum of Understanding

7. Reference

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.
3. Associated SOPs:EPHI-IRB SOP 008/02.0; EPHI-IRB SOP 010/02.0EPHI-IRB SOP 011/02.0; EPHI-IRBSOP 013/02.0

8. Annex

Annex 1:Contents of a Submitted Package (Checklist)
(EPHI-IRB AF 01-007/02.0)

Protocol Number:……..

☐**Initial Review Submitted Package**

- ❑ Protocol Summary Sheet
- ❑ Original Initial Review Application Form
- ❑ Office memo or supporting letter
- ❑ Protocol and Protocol-Related Documents

☐information for subjects ☐ informed consent form

☐case report forms (CRF) ☐ study budget

☐ Curriculum vitae (CV) ☐ GCP or research ethics training certificates

☐investigator's brochure ☐MoU

☐ Others……

☐**Resubmission for Re-review Submitted Package**

- ❑ Resubmission or "Correction" Memorandum
- ❑ Revised Protocol Summary Sheet (if submitted initially)
- ❑ Original Initial Review Application Form
- ❑ Protocol and Protocol-Related Documents

☐information for subjects ☐ informed consent form

☐case report forms (CRF) ☐ study budget

☐ Curriculum vitae (CV) ☐ GCP or research ethics training certificates

☐investigator's brochure ☐MoU

☐ Others……

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the document or the software package used to prepare the documents.

☐**Protocol Amendment Submitted Package**

- Request for Amendment Memorandum
- Original Amendment Submission Form
- Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

☐**Continuing Review Package**

- Request for Continuing Review Memorandum
- Original Continuing Review Application Form
- Current Informed Consent Document (last approved by the IRB)

☐**Final Report Review**

- Request for Final Report Review
- Original Final Report Review Application Form

☐**Protocol Termination Package**

- Request for Termination Memorandum
- Original Continuing Review Application Form (Termination Submissions are contained on this form).

Annex 2: Memorandum of Understanding Template
(EPHI-IRB AF 02-007/02.0)

LOG OF PARTNER INSTITUTION

MEMORANDUM OF UNDERSTANDING

THIS AGREEMENT is made as of [**INSERT DATE**]

BY AND BETWEEN:

1. **The Ethiopian Public Health Institute**, Federal Government Organ, established under council of ministers regulations number _____ with office located at Gulelle Arbegnoch Street, Gulelle Sub city, Addis Ababa, Ethiopia ("**EPHI**");

And

2. The [**NAME OF ENTITY**], [**TYPE OF ENTITY**] established under [**CONSTITUTING DOCUMENT**] with office located at [**FULL ADDRESS**], ("**ACRONYM**").

RECITALS

A. **Whereas**, EPHI is engaged in Public Health research, Public Health emergency management and National Laboratory Quality system establishment and [**NAME OF ENTITY**] is engaged in [**MAJOR LINES OF Engagement**];

B. **Whereas**, EPHI and [**NAME OF ENTITY**] each desires to conduct the scientific research described in Annex A hereto; and

C. **Whereas**, EPHI and [NAME OF ENTITY] believe that collaborating with each other in the performance of such research will be of mutual benefit, will further strengthen the health and benefits of Ethiopian people and will foster the development of scientific knowledge;

NOW, THEREFORE, in consideration of the promises and mutual covenants set forth herein, EPHI and [NAME OF ENTITY] agree as follows.

1. Definitions

In this, agreement the following words shall have the following meanings:

"Agreement"	shall means this MOU agreement including all attachments and schedules referred to herein;
"Arising Intellectual property"	shall means individually and collectively, all intellectual property made, conceived or developed during the term of this agreement and directly resulting from the research project carried out hereunder;
"Background Intellectual Property"	shall means, individually and collectively, all intellectual property developed, produced or obtained by a Party outside the scope of the research Project;
"Completion Date"	shall means the last day of the term described in Section;
"Effective Date"	shall means the date on which EPHI and [NAME OF ENTITY] signs this agreement;
"Intellectual property"	shall includes without limitation any right, or associated rights to all copyrights, trademarks, services marks, database rights, design rights, trade secrets, and patents;

"Parties"	shall means the EPHI and [**NAME OF ENTITY**]; Party means either one of them.
"Project"	shall means the activity described in Annex A;

2. Purpose of the agreement

This agreement between EPHI and [**NAME OF ENTITY**] defines the terms and conditions under which the parties undertake the [**BRIFE SENETENSE DISCRIBING THE PROJECT BRIFE SENETENSE DISCRIBING THE PROJECT**] in accordance with the research protocol entitled [**TITLE OF THE PROTOCOL**]

3. Objective of the project

The general objective of this project is (briefly describe the goal and the method or what is to be done and how) and provide evidence based information to the Federal Ministry of Health (stake holders, partners … if any)

4. Obligations of EPHI

EPHI shall:

4.1 Lead the design, protocol development, and the implementation (data collection, analysis and reporting) of the project;

4.2 Establish partnership and provide leadership for the successful completion of the project in the specified timeframe;

4.3 Make all efforts to achieve the goals and objective of the project using commonly accepted professional standards of workmanship and effort;

4.4 Organize the national dissemination workshops;

4.5 [Any additional responsibility]

4.6 [Any additional responsibility]

The detail roles and responsibilities of the parties are described in Annex A of this agreement

5. Obligations of [NAME OF ENTITY]

[NAME OF ENTITY] shall:

5.1 Provide technical assistance to EPHI in the design, implementation, data analysis and reporting of the project;

5.2 Build the capacity of EPHI's workforce and infrastructure;

5.3 Provide financial resources to support the project;

5.4 Provide technical and logistics assistance;

5.5 [Any additional responsibility]

5.6 [Any additional responsibility]

6. Financial arrangement

6.1 In consideration of the project described in Annex A and subject to the terms and conditions of the agreement [NAME OF ENTITY] will pay EPHI up to (total amount in USD) which shall be used exclusively for and in accordance with the project budget in Annex B.

6.2 [NAME OF ENTITY] shall pay the Grant Funds to EPHI in accordance with the schedule of project milestones in Annex B. more specifically:

A. First payment of ____% of total EPHI budget will be made upon signing by both parties of this MOU.

B. Second payment of___% of total EPHI budget will be made upon [Date]

C. Final payment of % ___of total EPHI budget will be made upon [Date]

6.3 EPHI will provide financial reports to_____. The report should show a clear accounting period for actual expenditures against the approved budget as and be set out using the financial report template appended in Attachment F. The financial report must be signed by EPHI's representative and authorized financial officer.

6.4 EPHI shall furnish, compile and make available at all reasonable times to [NAME OF ENTITY] any records, accounts financial statements or information, oral or written, which_____ may reasonably request in respect of the funds received by the EPHI.

6.5 [NAME OF ENTITY] Reserves the right on its own or through an agent to conduct an audit of all books, records, documents, and computer records relating to the grant fund at the EPHI premises.

6.6 EPHI will complete the Bank Information Form in Attachment D and return it with the signed copy of this Agreement. This will facilitate electronic payment to EPHI's account.

7. Report

Both parties shall collaborate to produce a report on the progress and the final result of the project.

8. Confidentiality

8.1 Each party undertakes in favor of the other that it will treat as confidential all results including any and all information whether of a technical, scientific and academic nature or otherwise relating in any manner to the business or affairs of the other party as may be communicated to it hereunder or otherwise in connection with this MOU and will not disclose such information to any person, any legal entity or to the media, and will not use such information other than for the purpose of this MOU, subject to any prior specific written authorization by the other party to such disclosure or use. The party receiving confidential information undertakes to treat all such information as secure and confidential and not to disclose the same to any unauthorized third party, without the disclosing party's prior written consent. The receiving party undertakes to likewise ensure that all of its employees, who are given access to such confidential information, are equally bound to this undertaking, during the term of this agreement and for a period of three years thereafter.

8.2 The obligations in clause 8.1 above shall not apply to data or information which the receiving party can clearly demonstrate:

a) was known to the receiving party prior to disclosure; or

b) was or becomes in the public domain through no fault of the receiving party; or

c) becomes available to the receiving party by an unconnected third party with the lawful right to make such a disclosure; or

d) has been independently developed or conceived by it; or

e) it is required to disclose by order of a court of competent jurisdiction.

f) reporting to parliament or other governmental organs mandated by law to oversee the activities of the recipients.

g) is approved for release in writing by an authorized representative of the other party.

9. Project data

EPHI remains a full owner of the project data (row data) and has the right to fully use the data for further analysis and publication. [NAME OF ENTITY] should request and get approval from EPHI if it intends to do any further analysis and publication using the project data other than those contained in deliverables.

10. Publication

Both parties shall have the right to jointly and severally disseminate and/or publish the findings resulting from and specific to the work completed under this agreement, all publications arising from the research which one party intends to publish will be submitted in writing to the other party detailing any results and any background that the party intends to publish, at least thirty (30) days before the date of the proposed submission for publication. One party may, by giving written notice to the other party ("a confidentiality notice"): require that party to delay the proposed publication for a maximum of three (3) month(s) after receipt of the confidentiality notice if, in the party's reasonable opinion, delay is necessary in order to seek patent or similar protection for any of the party's background or any results that are to be published; or prevent the publication of any of the party's background that is confidential information. The confidentiality notice must be issued within thirty (30) days after the party receives details of the proposed publication. If a confidentiality notice is not received within that period, the party may proceed with the proposed publication. For the avoidance of doubt, the parties will discuss and agree authorship for any publication relating to the research.

11. Intellectual property

11.1 Nothing in this agreement shall affect the ownership of intellectual property rights existing prior to this Agreement or generated outside the Project which one Party agrees to make available to the other in the course of the project (“Background”). If one party makes any of its background available to the other party in the course of the research, the party receiving such background shall treat it as confidential information disclosed under clause 8 above, and shall not disclose it to a third party nor use it for any purposes other than that for which it was made available to that party. Each party hereby agrees to make any background which is relevant to the research available, to

the extent which it is free to do so, to the other solely for the purposes of undertaking the research and the Project.

11.2 Any intellectual property create, generated or developed from, the research within the project (the Arising IP ") shall be owned jointly EPHI and [NAME OF ENTITY]. Each party shall be free to use the Arising IP for any purpose.

11.3 The parties agree that the process of commercializing the Joint IP shall be their joint responsibility. The parties will enter into a revenue sharing agreement, where necessary to do so, to agree a fair and reasonable distribution of any exploitation income arising from the Joint IP (after deduction of direct costs and reasonable fees).

11.4 For the avoidance of doubt, the ownership of results as described above shall apply whether the results have been made by any one of EPHI and [NAME OF ENTITY] or by the two Parties.

12. Duration

The term of this agreement will start on the effective date and will continue in effect until [ENDING PERIOD], unless terminated earlier in accordance with this agreement. The parties may, by written agreement, extend the term of the agreement.

13. Representatives and notice

Any notice or request required under the agreement shall be effective when delivered by hand, mail, email or facsimile to the attention of the designated representatives of the parties identified below. The parities shall notify one another of any change in their representatives.

For EPHI	**For** [NAME OF ENTITY]
Name_____	Name_____
Title_____	Title_____
Email_____	Email_____
Tel._____	Tel._____
P.O.Box_____	P.O.Box_____

14. Termination

14.1 This agreement may be terminated by either party forthwith by giving written notice to the other party if the other party commits a material breach of any of the terms of this agreement and if the breach is capable of remedy, fails to remedy it within sixty days after being given a written notice containing full particulars of the breach and requiring it to be remedied

14.2 In case of termination EPHI with in thirty days of the date of termination invoice EPHI in respect of all payments due by EPHI under this agreement and any non cancellable costs and commitments relating to the research project which have been incurred as at the date of termination of this agreement

14.3 Termination or expiry of this agreement shall not affect the right of either party against the other party in respect of the period up to and including the date of termination or expiry

15. General

15.1 **Headings:** The headings in this agreement are for ease of reference only; they do not affect its construction or interpretation.

15.2 **Assignment:** both parties shall not assign, delegate, sub-contract, charge, mortgage or otherwise transfer any or all of its rights and obligations under this Agreement without the prior written consent of Imperial, which shall not unreasonably be withheld.

15.3 **Illegal/Unenforceable Provisions:** If any part or any provision of this agreement shall to any extent prove invalid or unenforceable in law, including the laws of the European Union, the remainder of such provision and all other provisions of this agreement shall remain valid and enforceable to the fullest extent permissible by law, and such provision shall be deemed to be omitted from this agreement to the extent of such invalidity or unenforceability. The remainder of this Agreement shall continue in full force and effect and the parties shall negotiate in good faith to replace the invalid or unenforceable provision with a valid, legal and enforceable provision which has an effect as close as possible to the provision or terms being replaced.

15.4 **Waiver of Rights:** No failure to exercise or delay in the exercise of any right or remedy which any party may have under this agreement or in connection with this agreement shall operate as a waiver thereof, and nor shall any single or partial exercise of any such right or remedy prevent any further or other exercise thereof or of any other such right or remedy.

15.5 **No agency:** This agreement is not intended to establish, and shall not be construed by the Parties in the future as having established any form of business partnership between themselves.

15.6 **Entire Agreement:** This agreement (including its Schedules) supersedes all other agreements and understandings, whether written or oral, between the parties about the research and constitutes the entire agreement between the parties concerning the research.

15.7 **Third Parties:** Except as otherwise expressly provided for herein, nothing in this agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this agreement.

15.8 **Amendments:** Any amendments to this agreement shall be agreed in writing by both parties.

15.9 **Governing Law:** this agreement is made and shall be interpreted in accordance with Ethiopian law and subject to the exclusive jurisdiction of the Ethiopian courts.

AGREED by the parties through their authorized signatories:

For and on behalf of **ETHIOPIAN Public Health Institute**	For and on behalf of [**NAME OF ENTITY**]
_____	_____
Signed	Signed
_____	_____
Print name	Print name
_____	_____
Title	Title
_____	_____
Date	Date

Annex 3: Material Transfer Agreement Template
(EPHI-IRB AF 03-007/02.0)

LOG OF PARTNER INSTITUTION

MATERIAL TRANSFER AGREEMENT TEMPLATE

This Material Transfer Agreement (MTA) has been prepared for use by Ethiopian Public Health Institute (EPHI) in all transfer of biological material (samples, Isolates, DNA/RNA, derivatives) abroad.

Provider:_____

Recipient:_____

1. Scope of application

1.1 The application of this material transfer agreement shall cover materials sent to the recipient for research purpose or for laboratory service.

1.2 Research purpose shall mean research conducted on the transferred material in connection with a research protocol developed and conducted by:

a) Provider ☐
b) Recipient ☐
c) Collaboration between provider and recipient ☐

1.3 Laboratory service shall mean confirmatory test, referral, quality assurance etc. to be conducted by the recipient laboratory as per the request of the provider. ☐

2. Material

Provider agrees to transfer to recipient the Following biological materials/sample /provide detail description/_____

_____

_____

3. Project description

3.1 In case of material transferred for research purpose, the research protocol under which the material is going to be used shall be described with specificity and as much as possible indicate the specific experimental test to be conducted on the material. _____

3.2 In case of material transfer for laboratory service, the purpose and laboratory procedures and analysis to be conducted on the material shall be described _____

4. Obligation of the recipient

4.1 The recipient agrees:

a. that the material is to be used solely for the purpose outlined under 3.1 and 3.2 above as applicable.

b. that the material will not be used for commercial purposes such as screening, production or sale for which a commercialization license may be required.

c. not to use the material in humans, in clinical trials, or for diagnostic purposes involving humans without the written consent of the provider.

d. to comply with all national and international guidelines rules and regulations applicable to the Research Project and the handling of the research material.

e. to retain the material in a secure location on its premises and will not permit the material or any part of it to come into the possession or control of any other organization or any individual other than those employees who are involved in the project under direct supervision of the recipient.

f. to ensure that suitable systems are in place for the tracking of material while in its possession.

g. not to transfer the material in whole or in part to third parties without the relevant third party entering into a separate Material Transfer Agreement with the provider.

h. that the material will not be used either alone or in conjunction with any other information, to establish the individual identities of any of the subject from whom material was obtained.

4.2 In addition to what has be set for the above, incase material are transferred for laboratory service the materials shall not be used for any other purpose including without limitation any treatment, diagnostic research or evaluation purpose including publication.

5. Ownership of material

5.1 The material remains the property of the provider. There is no transfer or license or implied transfer or license of rights in the material from the provider to the recipient including all intellectual property rights. This agreement does not restrict the rights of the provider to distribute the material to other institutions

6. Publication

For research protocol developed and conducted by the provider, the right for publication shall unilaterally resides on the provider. In case of a research protocol developed and conducted by the recipient, the recipient may publish, otherwise publicly disclose, or submit for publication an article, manuscript, abstract or other material that includes the results of the use the materials in research after securing the consent of the provider, such consent not to be an reasonably withheld. The recipient agrees to acknowledge the role of the provider in any publication arising out of the recipient use of the materials.

7. Intellectual property rights

7.1 For research protocol developed and conducted by the provider, the provider shall own all right, title and interest in and to any data, result know-how, any patentable invention and other intellectual property that are generated by or on behalf of the provider in connection with the use of the material in the research **("know-how") ("invention")**.

7.2 For research protocol developed and conducted by the recipient, the recipient shall own all right, title and interest in and to any data, result know-how, any patentable invention and other intellectual property that are generated by or on behalf of the recipient in connection with the use of the material in the research **("know-how") ("invention")**. Recipient hereby grants to the provider royalty fee, worldwide, non-exclusive license to make, have made, use, and otherwise practice the invention/know how owned by the recipient for the purpose of research and teaching including use by Ethiopian government in its health care system and

for health policy formulation, programs and interventions benefiting the Ethiopian people.

7.3 In case of material transferred for laboratory service the provider shall have sole and exclusive right, title and interest in and to any result, evaluation, report, information, invention, improvement, writing, communications, underlying data, and other documentation prepared, generated, or developed by and on behalf of the provider. Unless otherwise expressly agreed by the provider any and all intellectual property and publication right in connection with the evaluation or generated from the evaluation (laboratory service) shall be owned and held exclusively by the provider.

8. Collaborative activities

Materials transferred by the provider to the recipient as the result of research collaboration, the publication and property right shall be determined by the project protocol and the MOU signed by the recipient and the provider.

9. Disclosure

Recipient shall promptly disclosed to provider any invention generated in the research. In addition, recipient shall provide the provider with written report summarizing the result of any use of the material in the research or any results obtained in any other use of the material every six month during the term of the agreement, including up on expiration or termination of this agreement. Such reports shall include a summary of all data, and all information, inventions, discoveries ,"know how" or any other intellectual property made or generated by or on behalf of the recipient relating to the material .The recipient shall provide to the provider copy of all such data including accepted publications, articles, abstracts, presentations etc…

10. No Responsibility/Indemnity

10.1 The provider does not take any responsibility for loss, damage, wastage or spoilage of the research material during or after shipment to the address provided by the recipient under conditions agreed to in the protocol on shipment of the samples. This research material is provided as a service to the research community. **IT IS BEING SUPPLIED TO RECIPIANT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Provider makes no representations that the use of the research material will not infringe any patent or proprietary right of third parties.

10.2 The provider will, not be liable to the recipient or the recipient scientist for any loss,claim or demand made by the recipient or made against the recipient by any other party due to or arising from the use, storage and disposal of the material by the recipient, except when cause by the gross negligence or willful misconduct of provide.

11. Return of material

The Material (and any copies thereof made by or in possession of or under the control of the recipient) shall be and remain the property of the provider and shall be immediately returned or if the provider so requires, destroyed (i) on termination of this agreement, or (ii) if the recipient is in breach of any provision of this agreement, and (iii) at any other time on request of the provider. If the recipient is required to destroy the materials then it will ensure that this is done in compliance with all applicable laws and regulations and will confirm in writing to the provider that the materials have been destroyed.

12. Duration

This agreement commence on the last signature date of this agreement ("Effective Date") and ending _____ Year/Month thereafter (the "**Term**") unless terminated earlier in accordance with this agreement. The term may be extended as mutually agreed in writing by the Parties.

13. Final provisions

13.1 The undersigned provider and recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

13.2 The provider will retain a copy (aliquot) of every sample sent abroad as much as possible for local research needs.

For Recipient:

Recipient's Investigator	Duly authorized
Signature	Signature
Date	Date
Mailing Address for Material:	Mailing Address for Notices
Tel:	Tel:
Email:	Email:

For provider:

Recipient's Investigator	Duly authorized
Signature	Signature
Date	Date
Mailing Address for Material:	Mailing Address for Notices:
Tel:	Tel:
Email:	Email:

Annex 4: Consent of DG/DDG/Directorate Director on protocols
(EPHI-IRB AF 04-007/02.0)

Date: DD/MM/YYYY

To: EPHI-IRB

From: …… (DG/DDG/Directorate Director)

Subject: Endorsement of submitted protocol

I have reviewed the project entitled "……," which is submitted by ……, Principal Investigator from my directorate. I endorse that the project is discussed and agreed by the responsible case team, andhave no objection for submission for consideration to be approved by EPHI-IRB. I concur with collaborating institution, the principal investigator and co-investigators included in the study and commit to shoulder directorate responsibility. I certify that the directorate will provide utmost support and closely monitor execution of the project. The directorate willalso report any protocol deviation and adverse event on human study participants that may happen at any time of project implementation.

Name of DG/DDG/Directorate Director: ……

Signature: ……

Date: ……..

Annex5: Document Receipt Form
(EPHI-IRB AF 05-007/02.0)

Protocol Number:		**Submitted date:**	
Type of Submission:	☐Initial Review ☐Resubmission for re-review ☐Protocol Amendments	☐Continuing Review of Approved Protocols ☐Final Report Review ☐Protocol Termination	
Protocol Title:			
Principal Investigator:			
Telephone number:		**Fax :**	
E-mail:		**Preferred Contact**	☐Phone ☐Fax ☐e-mail
Institute:			
Delivery route:	☐Post ☐E-submission ☐In Person		
For office use only			
Submitted Documents (Tick in the boxes)	☐Protocol Summary sheet ☐ Filled application form ☐ Office memo or supporting letter ☐ Protocol and related documents ☐ Information for subjects ☐ Informed consent form ☐ Case report forms (CRF) ☐ Study budget ☐ Curriculum vitae (CV) ☐GCP or research ethics trainingcertificates ☐Investigator's brochure ☐MoU ☐ Others……		

Documents submitted:	☐Complete ☐Incomplete **The submission will not be accepted if the submitted package are incomplete**	
Received by: (Name and signature)		
Date received:		

Note: *Please bring this receipt with you when contacting EPHI-IRB*