Standard Operating Procedures

The AHRI/ALERT Ethics Review Committee

Effective date: January 05, 2018

Third Edition

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1. PURPOSE

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing, and amending SOPs within the AHRI/ALERT ethics review committee. The SOPs will provide clear, unambiguous instructions so that the related activities in the ethics committee are conducted in accordance with the WHO Operating Guidelines for Ethical Review Committee that review biomedical research, National Guideline for Ethics Committees and ICH (International Conferences on Harmonization) Good Clinical Practice (GCP).

2. SCOPE

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the AHRI/ALERT ethics review committee.

3. RESPONSIBILITY

It is the responsibility of the ethics committee to formulate the SOP by following the same procedures, format and coding system when drafting or editing any SOP of the institute.

Secretariat of AHRI/ALERT Ethics Review Committee (AAERC):

- Co-ordinate's activities of writing, reviewing, distributing and amending SOPs
- Maintains on file all current SOPs and the list of SOPs
- Maintains an up-to-date distribution list for each SOP distributed
- Distributes the SOPs with a receipt to all users
- Ensures all ethics committee members and involved administrative staff have access to the SOPs
- Ensures the ethics committee member and involved staff are working according to current versions of SOPs

SOP team:

- Proposes required SOPs
- Selects the format and coding system
- Drafts the SOP in consultation with ethics committee members and involves the secretariat.
- Assesses the request for SOP revision in consultation with the secretariat and Chairperson.

The committee has agreed to have an AAERC office which is delegated to the secretariat. Further discussion will be done on how to organize it.

Ethics committee:

- ❖ Reviews and approves the SOPs
- ❖ The chairperson should sign and date receipt of the approved SOPs

Ethics committee members and involved secretariat staff:

- ❖ Sign and date when they receive the approved SOPs
- ❖ Maintain a file of all SOPs received
- ❖ Return all out-of-date SOPs to the secretariat

4. FLOW CHART

5. DETAILED INSTRUCTIONS

5.1. List all relevant AAERC procedures

- ❖ Write down step by step all AAERC procedures.
- ❖ Organize, divide and name each process.
- ❖ Make a list of SOPs with coding reference and effective dates (Annex AA 01-001)

5.2. Format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format SOP/XXX/YY.W will be assigned to each SOP item by Secretariat. XXX is a three-digit number assigned specifically to the SOP. YY is a two-digit number identifying the version of the SOP and W is a one-digit number identifying the version of SOP with minor changes in the SOP. The number of version should be started from 01 and the W should be started with 0, for example, SOP001/01.1 is the SOP number 001 version 01 with one minor revision i.e. 01.1.

Each annex will be given unique code number with the format AF/BB- XXX/YY.W. AF is the abbreviation for Annex Form. BB is a two-digit number identifying the number of the annex, for example AF/01-001/01.0 means Annex Form number one of the SOP/001/01.0

Each SOP will be prepared according to the standard template. Please refer to Annex 2 – AA 02-001

5.3. **Write and approve a new/revised SOP**

If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form (Annex 3 –AA 03-001). When the need for a new SOP has been identified and agreed on, a designated member of the SOP team will write a draft. The draft SOP will be discussed with ethics committee members and all relevant administrative staff. The people involved in that particular task should agree upon the SOP. The final version will be passed to the Chairperson for review and approval.

5.4. **Implement, distribute and file all SOPs**

- The approved SOPs will be implemented from the effective date.
- The approved SOPs will be distributed to the AAERC members and the relevant staff by the Secretariat according to the distribution list. (Annex 4 – AA 04-001). When a revised version is distributed, the old version will be destroyed.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the secretariat of the ethics committee and kept in the Ethics Committees office.

5.5. **Review and revise an existing SOP**

- Any member of the ethics committee, secretariat or administrative staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in Annex 5– (AA 005-001) to make a request.
- If the AAERC agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the decision to the person who made the request.
- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section 5.3).
- The Secretariat is expected to review the SOPs at least every 2 years and record the dates of review in the SOP Master file.

5.6. **Manage and archive superseded SOPs**

- Superseded SOPs should be retained and clearly marked “superseded” and archived in the historical file by the Secretariat.

6. GLOSSARY

Master SOP files	An official collection of the institute standard operating procedures (SOP) accessible to all staff, AAERC members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.

7. ANNEX

ANNEX 1	AF 01-001/	List of AAERC SOPs
ANNEX 2	AF 02-001	Standard Operating Procedures Template
ANNEX 3	AF 03-001	Document History
ANNEX 4	AF 04-001	Log of SOP Recipients
ANNEX 5	AF 05-001	Request for Revision of an SOP

8. REFERENCES

1. Relevant National and International Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) *www.who.int/tdr/publications/publications/* - accessed 11 February 2005)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. National Health Research Ethics Review Guideline. Addis Ababa, Ethiopia. 4th Edition revised in June 2005
4. Drug Administration and Control Authority of Ethiopia *www.daca.gov.et/Documents/GCP-narreted.pdf*

ANNEX 1 LIST of AAERC SOPs

AF 01-001
Page 1 of 2

LIST of AAERC SOPs

No.	List of SOPs	Code	Version	Effective date
1	Writing, reviewing, distributing and amending of Standard Operating Procedures	AA 001	03.0	5 January 2016
2	Preparation of Guidelines	AA 002	03.0	5 January 2016
3	Constituting an AAERC	AA 003	03.0	5 January 2016
4	Confidentiality / Conflict of Interest Agreements	AA 004	03.0	5 January 2016
5	Training Personnel and AAERC Members	AA 005	03.0	5 January 2016
6	Selection of Independent Consultants	AA 006	03.0	5 January 2016
7	Management of Protocol Submission	AA 007	03.0	5 January 2016
8	Use of Study Assessment Form	AA 008	03.0	5 January 2016
9	Expedited Review	AA 009	03.0	5 January 2016
10	Initial Review of Application Protocol	AA 010	03.0	5 January 2016
11	Review of New Medical Device Studies	AA 011	03.0	5 January 2016
12	Review of Protocol Amendments	AA 012	03.0	5 January 2016
13	Review of Resubmitted Protocol	AA 013	03.0	5 January 2016
14	Continuing Review of Study Protocol	AA 014	03.0	5 January 2016
15	Review of Final Reports	AA 015	03.0	5 January 2016

ANNEX 1

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No.	List of SOPs	Code	Version	Effective date
16	Non-Compliance/Violation Intervention	AA 016	03.0	5 January 2016
17	Response to Participants' Requests	AA 017	03.0	5 January 2016
18	Management of Study Termination	AA 018	03.0	5 January 2016
19	Monitoring and Evaluation of Serious Adverse Events (SAE) Reports	AA 019	03.0	5 January 2016
20	Site Monitoring Visit	AA 020	03.0	5 January 2016
21	Preparation of Meeting, Agenda, Minutes and Action letters	AA 021	03.0	5 January 2016
22	Emergency Meeting	AA 022	03.0	5 January 2016
23	Communication Records	AA 023	03.0	5 January 2016
24	Maintenance of Active Study Files	AA 024	03.0	5 January 2016
25	Archives and Retrieval of Documents	AA 025	03.0	2 May, 2009
26	Maintaining Confidentiality of AAERC Documents	AA 026	03.0	5 January 2016
27	Audit and Inspection of the AAERC	AA 027	03.0	5 January 2016
28	Glossary of Terms and Definition	AA 028	03.0	5 January 2016

ANNEX 2 Standard Operating Procedures Template

AF 02-001
Page 1 of 2

Standard Operating Procedures Template

Name of Institution AHRI/ALERT			
Title:	**Title which is self-explanatory and is easily understood**		
SOP No:	**SOP /00- /0-**	**Page:** -	**of** -

TITLE *Title which is self-explanatory and is easily understood*
Effective Date: Supersedes Review date: Author: Date: …… *(Name).* Approved by: Date: …… *(Name)*

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ANNEX 2
AF 02-001

Main Text:

1. **Purpose** - summarizes and explains the objectives of the procedure.
2. **Scope** – states the range of activities that the SOP applies to.
3. **Responsibility** – refers to person(s) assigned to perform the activities involved in the SOP
4. **Flow chart** – simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity.
5. **Detailed instructions** – describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.
6. **Glossary** – clarifies uncommon or ambiguous words or phases by explanation.
7. **Reference** – lists sources of the information given in the SOP.
8. **ANNEX** - documents that explain further or clarifies complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.

ANNEX 3 Document History

AF 03-001

Document History

(The first draft 001 of the SOP history should be produced as the output of the first circulation of the document and the final version is the version after the approval by the Chairperson)

Author	**Version**	**Date**	**Describe the main change**
Name	0.1	*dd-Mmm-yy*	First draft
Name	0.2	*dd-Mmm-yy*	Second draft
Name	01.0	*dd-Mmm-yy*	Final version
Name	01.1	*dd-Mmm-yy*	

ANNEX 4 Log of SOP Recipients

AF 04-001

Log of SOP Recipients

No.	Name of Recipients	SOP#	No. of Copies	Signature	Date
1	Chairperson	SOP/001/01.0 SOP/002/01.0 SOP/003/01.0			

ANNEX 5 Request for Revision of an SOP

AF 05-001

Request for Revision of an SOP

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintain this with the SOP until an authorized replacement is in place.

SOP/001/01.0		
Title:		
Details of problems or deficiency in the SOP:		
Identified by:	Date (D/M/Y):	
Discussed with:		
SOP revision required: ☐ **Yes** ☐ **No**		
If yes, to be carried out by whom?		
If no, why not?		
Date SOP re-finalized:		
Date SOP approved:		
Date SOP becomes effective:		

Table Of Contents

1. Purpose

This procedure describes how to prepare a new guideline or update an existing one as well as the layout and format of each guideline.

2. Scope

This SOP applies to any AAERC guidelines, and their amendment versions published and distributed by the institute.

The AHRI/ALERT Ethics Review Committee (AAERC) works according to international rules that must be described in written standard operating procedures (SOPs). The SOPs may be disclosed to authorities and individuals upon request. In order to maintain a transparent relationship with non-members of the AAERC, certain procedures will form guidelines for use by investigators, scientific experts and by the Institute personnel.

3. Responsibility

It is the responsibility of the AAERC Secretariat or designated persons to prepare or amend the Institute guidelines as and when the need arises. The designated persons will manage the preparation/amendment of the guidelines with the assistance of the Secretariat.

4. Flow chart

No.	Activity	Responsibility
1.	Numbering of Guidelines	AAERC Secretariat
	↓	
2.	Numbering of the Version	AAERC Secretariat
	↓	
3.	Contents and Layout of A Guideline	AAERC Secretariat
	↓	
4.	Approval of New and Updated Guidelines	AAERC Chairperson /Member
	↓	
5.	Information for Personnel	AAERC Members / Secretariat
	↓	
6.	Distribution of Guidelines	AAERC Secretariat

5. Detailed Instructions

5.1. Numbering of the Guidelines

- Procedure SOP# AA 001 lists all procedures and guidelines used by the AAERC.
- When a new guideline will be created, a subsequent number should be allocated at the end of the list of existing Guidelines.
- When a guideline is no longer used, its status is changed to "inactive". It is not allowed to reuse the number of an inactive guideline.
- All guidelines are named and numbered in the following way: GL 01 to GL 99

5.2. Numbering of the Version

Number guideline versions as follows:

- Draft versions:

All draft versions are always indicated as "version 1.0" followed by the word "draft". For example: ***Version 1.0, draft***

- For minor changes on a final version:

Version V.0, final to ***Version V.n, final***

For example, the third update concerning minor issues on "version 2.2, final" will be indicated as "version 2.3, final".

- For major changes on a final version:

Version V.n, final to ***Version (V+1).0, final***

For example, major changes on "version 2.3, final" will be indicated as "version 3.0, final".

5.3. Contents and Layout of a Guideline

A new or updated guideline has five sections:

1. Cover Page
2. Table of Contents
3. Main text
4. References
5. Appendices

Sections 1 to 3 are mandatory. The *"Appendices"* section is not mandatory.

5.3.1. Cover Page

The cover page will have the following information:

- ❖ Logo of the AAERC, if any, Institute and related information (address, telephone number, fax number, email address).
- ❖ Title and number of the guideline date of implementation of the guideline
- ❖ Date of the previous versions: If not applicable, the date of previous version is indicated by "N/A" (= not applicable).
- ❖ Name (directory names and path included) of the corresponding computer document, if relevant.
- ❖ Name of the editors and address of the contact office.
- ❖ A copyright declaration.
- ❖ Refer to ANNEX (AA 01-002) for an example of a cover page.

5.3.2. Table of Contents

The table of contents lists all major headers and subheadings of the guideline, including the appendices and page numbers on which these appear in the guideline.

5.3.3. Main Text

- ❖ Introduction
  - ➢ Summarize and explain the purpose of the guideline.
  - ➢ A short note on how the guideline was prepared.
  - ➢ A short note on how to use the guideline.
- ❖ Detailed description
  - ➢ The final text should be short and clear.
  - ➢ Long guidelines should be split into shorter ones.
  - ➢ Wherever possible and relevant references should be added.
  - ➢ Limitation of the guidelines may be mentioned.

5.3.4. Appendices

- ❖ Replace long and complex descriptions.
- ❖ "Descriptions-by-example" are always recommended to avoid writing difficult and hard to understand texts.
- ❖ Glossary
- ❖ Full form of abbreviations

5.4. Approval of New and Updated Guidelines

- ❖ The members of the AAERC prepare a new guideline or update an existing guideline.

- ❖ The Chairperson of the AAERC and the Director of the Institute should approve each new or updated guideline.

5.5. Information for Personnel

- ❖ All members of the AAERC must read and understand a new or updated guideline.
- ❖ Each member will sign a form indicating that they have read and understood each new or updated guideline.
- ❖ Refer to ANNEX 2 (AF 02-001) for an example.
- ❖ If the guideline is for investigators/students/institute personnel, then they should be given a copy of the guideline and sign for receipt.

5.6. Distribution of Guidelines

- ❖ Guidelines are not confidential and may be disclosed for use by investigators, scientific experts and AAERC members.
- ❖ A Log of Guideline Distribution should be maintained for inventory records (ANNEX 3, AA 03-002).

6. Glossary

Guideline any suggestion, rules, etc., intended as a guide for specific practice

7. ANNEX

ANNEX 1	AF 01-002	Cover page of a Guideline (2
ANNEX 2	AF 02-002	List of Signatures
ANNEX 3	AF 03-002	Log of Guideline Distribution

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. National Health Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th edition, 2014.

ANNEX 1

Form AF 01-002
Page 1 of 2

Cover page of a Guideline

Guideline for

.....

.....

Version No…

Address:

ANNEX 1
Form AF 01-002
Page 2 of 2

Information on the Back of the Cover Page

Number of Copies
Printed Title of the Guideline Version No.

Month/Year of Publication

ISBN:

Author:
Editor:
Publisher:

Computer Record

ANNEX 2

Form AF 02-002

LIST OF SIGNATURES

Title of the Guideline:_____

Number of the Guideline: GL_____

The following listed persons have read this guideline and signed for this.

No.	Full Name of AAERC members	Signature	Date

ANNEX 3

Form AF 03-002

Log of Guideline Distribution

#	Name of Recipients	Affiliation	Guideline #	No. of Copies	Date

Table of Contents

1. Purpose

The AAERC was originally established in 1986 and has been functioning since then in order to provide independent guidance, advice, and decision (in the form of "approval/recommendation/stipulation/ disapproval") on health research or other specific research protocols involving human subjects. These guidelines will provide an additional tool to improve the day-to-day activities of the AAERC.

The AAERC is composed of both scientists and non-scientists. It is independent in its reflection, advice, and decision.

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for constitution, responsibilities, and activities of the Institutional Ethics Committee /Institutional Review Board (AAERC). The TOR is further supported by the Standard Operating Procedures of AAERC

2. Scope

The SOP applies to all activities under the AAERC

3. Responsibility

It is the responsibility of the AAERC members, secretariat to read understand and respect the rules set by the AAERC

4. Flow Chart

No.	Activity	Responsibility
1.	Ethical basis/Guidelines	AAERC Members, Secretariat
	↓	
2.	Composition of the AAERC	AAERC Members and Secretariat, AHRI/ALERT Director
	↓	
3.	Membership Requirements	AAERC Members and Secretariat
	↓	
4.	Resignation, Disqualification, Replacement of Members	AAERC Members and Secretariat, AHRI/ALERT Director
	↓	
5.	Independent Consultants	AAERC members and Secretariat

5.1	Recommendation	AHRI/ALERT Director
	↓	
5.2	Invitation letter	AAERC Members and Secretariat
	↓	
6.	Conditions of Appointment	AAERC Chairperson and Vice-Chairperson
	↓	
7.	Officers	
	↓	
8.	Secretariat	AAERC Secretary
	↓	
9.	Quorum Requirements	AAERC Members and Secretariat
	↓	
10.	Dissolving of the AAERC	AAERC Members and Secretariat

5. Detailed Instructions

5.1. Ethical basis

- The AAERC recognizes that the protocols it approves may also be approved by national and/or local ethics committees prior to their implementation in specific localities.
- In evaluating protocols and ethical issues, the AAERC is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world and within the country itself.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed AHRI/ALERT research is being considered.
- The AAERC also seeks to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research it has approved.
- The AAERC is guided in its reflection, advice, and decision by the ethical principles expressed in the Declaration of Helsinki (1964 and subsequent revisions).
- It makes further reference to the National and International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), the Belmont Report, and the European Convention on Human Rights and Biomedicine.
- The AAERC establishes its own standard operating procedures based on the Operational Guidelines for Ethics Committees That Review Biomedical Research (WHO), the WHO & ICH Guidelines for Good Clinical Practice and the local regulations.

- The AAERC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations according to the most recent guidelines.

5.2. **Composition of the AAERC**

- The AAERC is composed of at least 5 voting members
- The members shall include at least one member whose primary concerns are in medical science, at least one member whose primary concerns are in non-medical/non-scientific areas, and at least three members from outside the Institute.
- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the Institute.
- Professional qualifications include Immunologist, Microbiologist, Physician, Internist, Dermatologist, Dermatopathologist, Pharmacist, Nurse, Social Scientist, Lawyer, Statistician, Paramedic and at least one Layperson.
- The AAERC cannot consist entirely of men or entirely of women.
- The AAERC should have representatives from the older and younger generations.

5.3. **Membership requirements**

- New members will be nominated by members of AAERC and approved by a full board meeting
- The Director of AHRI is responsible for handling the appointment of committee members proposed by the ethics committee
- Members are selected in their personal capacities, based on their interest, ethical and/or scientific training, knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the AAERC work.
- Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.
- The AAERC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision, refer to SOP# AA 004 - Confidentiality / Conflict of Interest Agreement.
- Members will be required to sign a confidentiality agreement at the start of their term.
- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the AAERC in the course of its work.

- ❖ Members are appointed for a period of 3 years.
- ❖ Their appointments may be renewed by the Director of the AHRI/ALERT for up to two consecutive terms.
- ❖ The Ethics Committee will include some rotation after a period of three-year for up to two consecutive terms, but it will also strive to ensure continuity within the AAERC by staggering replacement of members.

5.4. **Resignation, Disqualification, Replacement of Members**

- ❖ Members may resign their positions by submitting a letter of resignation to the Chairperson.
- ❖ Members may also be disqualified from continuance. The Chairperson should provide written arguments to the (other) members and there should be unanimous agreement.
- ❖ Members that have resigned or have been disqualified may be replaced by selection and appointment of new members proposed by the ethics committee

5.5. **Independent Consultants**

- ❖ Independent Consultants may further support the AAERC in its reflections on specific protocols or requests for advice on specific ethical issues.
- ❖ Independent Consultants are proposed by the committee and approved by AAERC Chairperson. The selected Independent Consultants will then be appointed by the AHRI Director.
- ❖ Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, social science, law, ethics, and religion. Independent Consultants are appointed for the duration of the period sought (see SOP# AA 006).

5.6. **Conditions of Appointment**

- ❖ Members and Independent Consultants are appointed to the AAERC under the following conditions:
  - ➢ Willingness to publicize his/her full name, profession, and affiliation.
  - ➢ All financial accountability, reimbursement for work and expenses, if any, within or related to the AAERC should be recorded and made available to the public upon request;
  - ➢ All AAERC Members and Independent Consultants must sign Confidentiality /

Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

5.7. **Officers**

- The following officers through their respective responsibilities contribute to the good functioning of the AAERC:

Chairperson	Responsible to chair the meetings and liaise directly with the Director of AHRI/ALERT, report the meeting outcomes to the Director, invite independent consultants to provide special expertise to the AAERC on proposed research protocol. Responsible for preliminary review of protocols and assign reviewers for expedited review protocols based on the areas of expertise. Approves expedited review process then report to Board. Responsible in preparation of the agenda
Vice-Chairperson	Responsible to chair the meetings in the absence of the Chairperson and act as vice-chair during meetings with the Chairperson and conduct all activities under the mandate of the chairperson in her/ his absence, review protocols in his/ her areas of expertise.
Secretariat	Responsible for the administrative aspect of the AAERC (see5.8 - below)

- The Chair and the vice chair (officers) are elected by the AAERC members by voting for a two-year term. They may be re-elected but not for more than two consecutive terms. Should they resign or be disqualified; the AAERC members elect a replacement until the completion of the normal term.

5.8. **Secretariat**

- The Secretariat is composed of the AAERC Chairperson, secretary and the administrative supporting staff.
- The supporting staff are staff members of AHRI/ALERT appointed by the AHRI/ALERT Director
- The Secretariat shall have the following functions:
  - Organizing an effective and efficient tracking procedure for each proposal received (see SOP# AA 007, 024).
  - Preparation, maintenance and distribution of study files (see SOP# AA 024)

- Organizing regular AAERC meetings (SOP# AA 021).
- Preparation and maintenance of meeting agenda and minutes (see SOP# AA 021)
- Maintaining the AAERC documentation and archives (See SOP# AA 010 and AA 025)
- Communication with the AAERC members and applicants (SOP# AA 023)
- Arrangement of training for personnel and AAERC members (see SOP# AA 005)
- Organizing the preparation, review, revision and distribution of SOPs and guidelines (see SOP# AA 001 and AA 002)
- Providing the necessary administrative support for AAERC related activities to the Chairperson of the Committee (e.g., communicating a decision to the applicant - SOP# AA 023, AA 007- AA 017)
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

5.9. **Roles and responsibilities of AAERC members**

- Participate in the AAERC meeting
- Review, discuss and consider research proposals submitted for evaluation
- Monitor serious adverse event reports and recommend appropriate action(s) (SOP# AA 019)
- Review the progress reports and monitor ongoing studies as appropriate
- Evaluate final reports and outcomes
- Maintain confidentiality of the documents and deliberations of AAERC meetings (SOP# AA 025)
- Declare any conflict of interest
- Participate in continuing education activities in biomedical ethics and biomedical research
- Perform other related activities

5.10. **Quorum Requirements**

- A minimum of 50% of the members must be present at a meeting in order to issue a valid advice and/or decision.
- Professional qualifications of the quorum requirements should consist of:
- At least one member whose primary area of expertise is in a non-scientific area, one

medical scientist and at least one member who is independent of the institution/research site.

5.11. **Dissolving of the AAERC**

- ❖ At any point in time, should the AHRI/ALERT cease to exist, the AAERC is automatically dissolved.
- ❖ The Director of AHRI/ALERT, following written notification to each of the members, may also dissolve the AAERC at any time.
- ❖ Upon AHRI/ALERT breach of ethics
- ❖ Upon failure to perform duties and responsibilities specified in this SOP

6. Glossary

Confidentiality	Prevention ofdisclosure,to otherthan authorized individuals, of AAERC information and documents
AAERC	AHRI/ALERT Ethics Review Committee is an independent committee whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a research project and to provide public assurance of that protection.
Scientists	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed.

7. ANNEX

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice
   (ICH GCP) 1996.
3. Related SOPs: SOP# AA 002, 004-005, 007-017, 019, 021, 023, 024, 025.

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1. Purpose

The purpose of this section is to provide a form of Confidentiality / Conflict of Interest Agreement and identify who should read, understand, accept, keep in mind, sign and date the form. The procedures provide details when and where to sign as well as how the signed document should be kept.

2. Scope

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the AAERC.

3. Responsibility

It is the responsibility of all newly appointed AAERC members to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the AAERC to protect the rights of study participants.

4. Flow chart

No.	Activity	Responsibility
1	Read the text carefully and thoroughly ↓	AAERC members / guest attendees / observers
2	Ask questions, if any ↓	AAERC members / guest attendees / observers
3	Sign to indicate consent ↓	AAERC members / guest attendees / observers
4	Keep the Agreement in mind.	AAERC members / guest attendees / observers

5. Detailed instructions

5.1. Read the text carefully and thoroughly.

- ❖ Newly appointed members obtain two copies of the Agreement Form AF 01-004.
- ❖ Read through the text of the form very carefully.
- ❖ The members fill in their names and their office on the blanks.

5.2. Ask questions, if any.

- ❖ Direct questions to the Secretariat, if any part or sentences is not clear.
- ❖ Let the officer explain or clarify the contents of the document.

5.3. Sign with consent.

- ❖ Sign and date both copies at the document before a member of the Secretariat.
- ❖ Give the forms back to the secretary to sign and date.
- ❖ The members keep a copy for their records.

5.4. Keep the Agreement in mind.

- ❖ The AAERC Secretariat keeps a copy of the signed Agreement as the Institute's records.
- ❖ Keep the copies in a Confidentiality/Conflict of Interest Agreement file.
- ❖ Store the file in a secure cabinet with limited key holders.

6. Glossary

Confidentiality	Thenonoccurrenceofunauthorizeddisclosureof information:
Confidentiality Agreement	Sometimes called Secrecy or Nondisclosure agreements An agreement designed to protect information, expertise and other trade secrets from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.

Conflict of Interest A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

There are three key elements in this definition: financial interest; official duties; professional interest.

A conflict of interest occurs when:

- An individual's private interest differs from his or her professional obligations to the institute.
- Professional actions or decisions occur that an independent observer might reasonably question.
- A conflict depends upon situation and not on the character or actions of the individual.
- Potential conflicts of interest must be disclosed and managed as per policy.

7. ANNEX

ANNEX 1	AF 01-004	Confidentiality / Conflict of Interest Agreement Form
ANNEX 2	AF 02-004	Confidentiality Agreement for Guest/Observer Attendance to AAERC Meeting
ANNEX 3	AF 03-004	Confidentiality Agreement for Non-members Requesting Copy (ies) of AAERC Documents

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

3. National Health Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th edition, 2014.

ANNEX 1 Confidentiality / Conflict of Interest Agreement Form
AF 01-004
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Confidentiality / Conflict of Interest Agreement Form

In recognition of the fact, that I_____member's name, and his/her affiliation…herein referred to as the "Undersigned", has been appointed as a member of AAERC has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines.

Whereas the appointment of the undersigned as a member of AAERC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest.

Whereas the fundamental duty of an AAERC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review.

Whereas AAERC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and wellbeing of human subjects;

The undersigned, as a member of the AAERC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of AAERC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade and other

secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of AAERC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

ANNEX 1

AF 01-004

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Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in AAERC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of AAERC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the AAERC.

The Undersigned will immediately disclose to the Chairperson of AAERC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an AAERC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the AAERC review or approval except to provide information requested by the Committee.

Examples of conflict-of-interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

ANNEX 1

AF 01-004

Page 3 of 3

Agreement on Confidentiality and Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the AAERC. A copy will be given to you for your records.

In the course of my activities as a member of the AAERC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I_____ have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Undersigned Signature — Date

_____ _____

Director of AHRI/ALERT — Date

ANNEX 2 Confidentiality Agreement Form for Guest Attendees to IEC/IRB Meetings
AF 02-004

Confidentiality Agreement Form
For Guest Attendees to IEC/IRB Meetings

I,_____, understand that I am allowed to attend the AAERC meeting as a guest or an observer. In the course of the meeting of the AAERC, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as Confidential.

Indicate the details (date and number) of the AAERC meeting attended:

_____

_____

_____s

Signature of the Guest or Observer — Date

_____ _____

Chairperson of AAERC — Date

ANNEX 3 Confidentiality Agreement Form For Non-members Requesting Copies of AAERC Documents

AF 03-004

Confidentiality Agreement Form
For Non-members Requesting Copies of AAERC Documents

I_____, as a non-member of AAERC, understand that the copy (ies) given to me by the AAERC is (are) confidential. I shall use the information only for the indicated purpose as described to the AAERC and shall not duplicate, give or distribute these documents to any person(s) without permission from the AAERC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following AAERC documents:

_____

_____

_____

_____

Signature of the recipient

Date

_____ _____

Chairperson of AAERC

Date

Table of Contents

1. Purpose

The purpose of this section is to inform the AAERC personnel and members why training is necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

AHRI/ALERT recognizes the importance of training and continuing professional development; therefore, the institution will allocate an annual budget for (subject to availability of funds) specific training and study visits for AAERC personnel and members. New AAERC members are required to undergo an initial training program prior to joining the Committee. All members are required to have continuous training at least once a year.

2. Scope

The SOP applies to all personnel of the AAERC.

3. Responsibility

It is the responsibility of the AAERC members to have themselves educated and trained periodically.

4. Flow chart

No.	Activity	Responsibility
1.	Topics for training	AAERC members / secretariat/ staff
	↓	
2.	How to get trained	AAERC members / secretariat/staff
	↓	
3.	Keeping the training record.	AAERC members / secretariat/staff

5. Detailed instructions

5.1. Topics for training

AAERC members should maintain competence by ensuring currency of their knowledge of:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- Ethical Issues
- Relevant laws
- Developments in relevant science, technical and environmental, health and safety aspects
- Relevant requirements of health, safety and environmental laws and regulations and related documents
- Audit procedures.
- Other relevant topics

An interchange of ideas, information and experiences with national and overseas institutions and organizations related to research ethics is also being carried out. International cooperation is also necessary to discuss ways of tackling harmful information distribution and joint efforts to tackle such distribution patterns. Efforts are being made to collect information on overseas trends and to attend international specialist meetings organized for the exchange of experience and information.

5.2. How to get trained

- Get information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards and various media channels.
- Select the ones you need.
- Register to attend.
- Identify funding sources
- Inform AAERC chairperson and Secretariat

5.3. Keeping the training records

- Fill in the form AF 01-005 to record the training/workshop/conference activities in chronological order.

- ❖ Make a copy of the form.
- ❖ Keep the original form as your record.
- ❖ Give the copy to the secretariat staff to keep in the AAERC file.

6. Glossary

Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Workshop	A group of people engaged in study or work on a creative project or subject

7. ANNEX

ANNEX 1 AF 01-005: Training Record Form

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. National Health Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014.

ANNEX 1 Training Record Form

AF 01-005

Training Record Form

First name:		Last name:
Staff / Membership since:		Status:
Educational Background:		
Work Experience:		
Training Experience:		

#	Courses / Workshops / Conferences / Meetings Attended	Organized by:	Where?	Duration	Source of Funding
1					
2					
3					
4					

Table of Contents

1. Purpose

The purpose of this SOP section is to provide procedures for engaging the expertise of a professional as a consultant to the AAERC.

2. Scope

If the Chairperson or the AAERC determines that a study will involve procedures or information that is not within the area of expertise of the AAERC members, the Chairperson or the AAERC may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the AAERC.

3. Responsibility

Upon the advice or recommendation of the secretariat or any AAERC member, it is the responsibility of the AAERC to nominate and approve the name of the special consultants to be signed by the Chairperson.

4. Flow chart

No.	Activity	Responsibility
1.	Selection of Independent Consultants	AAERC Members Secretariat
	↓	
2.	Consultation Services	AAERC Secretariat / Consultant
	↓	
3.	Termination of the Services	Consultant / AAERC

5. Detailed instructions

5.1 Selection of Independent Consultants

- Identify the experts by the AAERC member and Secretariat.
- Nominate the consultants.
- Conduct a qualification review of the prospective consultant
- Make decision based on expertise, availability and independence criteria
- Get approval from the AAERC.
- Contact the consultant.
- The consultant provides:

- A curriculum vitae
- A signed Professional Services Agreement (AF 01-006, see ANNEX 1of this SOP).
- A signed Confidentiality/Conflict of Interest Agreement (AF 03-006, ANNEX 3 of this SOP)

❖ Keep the documents in the consultant's file.

❖ Create a roster of consultants and the areas of their expertise.

5.2 Consultation Services

❖ AAERC provides study protocol documents to the appropriate consultant for review.

❖ The consultant must complete a consultative report to be reviewed by the AAERC at the time the study is reviewed.

❖ The consultant may attend the AAERC meeting, present the report and participate in the discussion but cannot vote.

❖ The report becomes a permanent part of the study file.

5.3 Termination of the Services

❖ Consultation services may be terminated by either the consultants themselves or by the AAERC.

❖ Upon termination of the consultant's services, a member of the Secretariat ensures that all the qualifying documentation and the reason for discontinuation of the services are filed with the administrative documents.

6. Glossary

Independent consultant	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocol.

7. ANNEX

ANNEX 1	AF 01-006	Professional Services Agreement Form
ANNEX 2	AF 02-006	Consultant Report Form
ANNEX 3	AF 03-006	Confidentiality / Conflict of Interest Agreement Form

8. Reference

1. AAERC SOP: SOP # AA 004

ANNEX 1 Professional Services Agreement Form

AA 01-006

Professional Services Agreement Form

Whereas the fundamental duty of the AAERC is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review.

Whereas the AAERC might occasionally require the services of a specialized expert to advise it on a particular project in order to ensure that sufficient thought is given to important aspects or details that might otherwise be missed or misunderstood

Therefore,

This agreement is entered between …. *independent consultant name, and his/her affiliation…. as independent consultant* (henceforward named as the Consultant) and AAERC for the Independent Consultant to review the project… (*insert name*)…. submitted by …. *(insert names)*….. and assess whether the proposed research involving human subjects ensures that the studies are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines and submit an unbiased report to the AAERC within …… (*state period).*

The Independent Consultant must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and wellbeing of human subjects.

The appointment of the undersigned as an independent consultant of AAERC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest.

The AAERC will provide the independent consultant with the full project proposal and annexes, if any, which will be returned with the report to the AAERC, at the end of the consultancy.

The Consultant will be responsible for the evaluation, research and analysis of any relevant background, current status and knowledge in the field of study and related matters to ensure adequate understanding of the protocols and procedures in the proposed research that will help him/her reach a conclusion, make appropriate judgment or provide an unbiased opinion.

The Independent consultant will submit a written report to the AAERC. The report will contain recommendations for the AAERC regarding the ethical standard of the project under review. The AAERC might request the Consultant to attend an AAERC full board meeting.

As part of this agreement, the independent consultant will sign a Conflict of Interest and

Confidentiality agreements.

The Independent Consultant will receive the sum of …. *(state)* for the service upon submission of an adequate report…. (*Or if in installments, describe conditions and sum*) …from AHRI/ALERT.

The Director of AHRI/ALERT (see below) ensures that the payment is made to the consultant when the AAERC Chairperson confirms receipt of a written report.

Signature (consultant) _____ Dated _____

Signature (AAERC Chairperson) _____ Dated _____

Signature (Director, AHRI/ALERT)_____ Dated _____

ANNEX 2 Consultant Report Form

AA 02-006

Consultant Report Form

Project title:

Background:

Procedures:

Ethical concerns:

Analysis:

Recommendations:

Reference materials:

Signature_____ Date_____

ANNEX 3 Confidentiality / Conflict of Interest Agreement Form

AF 03-006
Page 1 of 3

Confidentiality / Conflict of Interest Agreement Form

In recognition of the fact, that I…. *independent consultant name, and his/her affiliation*…. herein referred to as the "Undersigned", appointed as an independent consultant of AAERC have been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines.

Whereas the appointment of the undersigned as an independent consultant of AAERC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest.

Whereas the fundamental duty of an AAERC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review.

Whereas AAERC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and wellbeing of human subjects.

The undersigned, as an independent consultant of the AAERC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties an independent consultant of AAERC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade and other

secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of AAERC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in AAERC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of AAERC that no member/ independent consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the AAERC.

The Undersigned will immediately disclose to the Chairperson of AAERC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an AAERC independent consultant has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the independent consultant in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When an independent consultant has a conflict of interest, he/she should notify the Chairperson and may not participate in the AAERC review except to provide information requested by the Committee.

Examples of conflict-of-interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the AAERC. *A copy will be given to you for your records.*

In the course of my activities as an independent consultant of the AAERC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as an independent consultant.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I_____have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____
Undersigned Signature Date

_____ _____
Director of AHRI/ALERT Date

Table of Contents

1. Purpose

This standard operating procedure is designed to describe how the Secretariat of the Institutional Ethics Committee / Institutional Review Board (AAERC) manages protocol submissions to the AAERC.

2. Scope

Protocol submissions include:

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

3. Responsibility

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

4. Flow chart

No.	Activity	Responsibility
1.	Receive Submitted Packages	AAERC Secretariat
	↓	
2.	Check for submission items on checklist: ❖ Initial Review Application ❖ Exemption of protocol ❖ Resubmission of Protocols with Corrections ❖ Protocol Amendment ❖ Continuing Review of Approved Protocols ❖ Protocol Termination	AAERC Secretariat
	↓	
3.	Complete the submission process	AAERC Secretariat
	↓	
4.	Store the received packages	AAERC Secretariat

5.Detailed instructions

5.1 Receive submitted packages

5.1.1 Initial Review Application

- ❖ Go to 5.2.

5.1.2 Protocol exemption

- ❖ Go to step 5.2.1.2

5.1.3 Resubmission of Protocols with Corrections

- ❖ Retrieve the previous receipt form from the Secretariat's records.
- ❖ Go to step 5.2.1.3

5.1.4 Protocol Amendment

- ❖ Retrieve the previous receipt form from the Secretariat's records.
- ❖ Go to step 5.2.1.4

5.1.5 Continuing Review of Approved Protocols

- ❖ Retrieve the previous receipt form from the Secretariat's records.
- ❖ Go to step 5.2.1.5

5.1.6 Protocol Termination

- ❖ Retrieve the previous receipt form from the Secretariat's records.
- ❖ Go to step 5.2.1.6

5.2 Check for submission items

5.2.1 Get relevant forms:

5.2.1.1. Initial Review Application

- ❖ a checklist for contents of a submitted package, form AF 01-007 (see ANNEX 1),
- ❖ a document receipt form, AA 02-007, (see ANNEX 2) and
- ❖ an application form for initial review, AF 01-010, (see ANNEX 1 of SOP# AA 010).
- ❖ Go to step 5.2.2.
- ❖ For e-submission, go to 5.2.3 (Filled AF 01-010 should be attached).

5.2.1.2. Protocol exemption

- ❖ a checklist for contents of a submitted package, form AF 01-007 (see ANNEX 1),
- ❖ a document receipt form, AF 02-007, (see ANNEX 2) and
- ❖ an application form for initial review, AF 01-010, (see ANNEX 1 of SOP# AA 010).
- ❖ Go to step 5.2.2.

- ❖ For e-submission, go to 5.2.3 (Filled AF 01-010 should be attached).

5.2.1.3. Resubmission of Protocols with corrections

- ❖ a checklist form (AF 01-007, see ANNEX 1),
- ❖ a document receipt form (AF 02-007, see ANNEX 2) and
- ❖ a review form (AF 01-013 in ANNEX 1 of SOP# AA 013)
- ❖ Go to step 5.2.2

5.2.1.4. Protocol Amendments

- ❖ a checklist for contents of a submitted package, form AF 01-007 (see ANNEX 1),
- ❖ a document receipt form, AF 02-007, (see ANNEX 2) and
- ❖ a re-review report form, AF 01-012, (ANNEX 1 of SOP# AA 012)
- ❖ Go to step 5.2.2

5.2.1.5. Annual Continuing Reviews of Approved Protocols

- ❖ a checklist for contents of a submitted package, form AF 01- 007 (see ANNEX 1),
- ❖ a document receipt form, AF 02-007, (see ANNEX 2) and
- ❖ a re-review report form, AF 01-014, (ANNEX 1 of SOP# AA 014)
- ❖ Go to step 5.2.2

5.2.1.6. Protocol Termination

- ❖ a checklist for contents of a submitted package, form AF 01- 007 (see ANNEX 1),
- ❖ a document receipt form, AF 02-007, (see ANNEX 2) and
- ❖ a re-review report form (AF 01-015 in ANNEX 1 of SOP# AA 015) Go to step

5.2.2 Fill in the forms:

- ❖ Give the form AF 02-007 and the form AF 01-010 to 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 AF 01-007, (ANNEX 1).
- ❖ 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 Protocol-Related Documents

- 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
  - Abstract
  - Type of Protocol (screening, survey, clinical trial and phase)
  - 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
  - Efficacy or Evaluation Criteria (Response/Outcome)
  - Safety Parameters Criteria (Toxicity)
- Check the submitted Protocol and Related Documents for the following contents:
  - Subjects' information sheets
  - Informed Consent Form
  - Case Record Form (CRF)
  - Study budget and budget justification
  - Agreement of the study
  - Curriculum Vitae (CV) of investigators
  - Investigators' Brochure
- 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 AAERC 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: E:AAERC\year\protocols\protocol number and PI.
- ❖ 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 6 digits with running number of the year in the first two boxes, then slash sign and the last two digit of the year, followed by a dash sign and the month.

  For example, 01/03-01 means protocol number one submitted in Jan.2003.
- ❖ 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.

5.2.5 Create 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 Complete the submission process

- ❖ Get the Form AF 02-007 and AF 01-010 back 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 AF 02-007.
- ❖ Return the original copy of the AF 02-007 to the applicants for their records.
- ❖ Attach the filled checklist (AF 01-007) with the copy of the form AF 02-007 with a staple.
- ❖ Keep the copy of the document receipt form in the "***Protocol Receipt***" file.
- ❖ Attach an Initial Review Application Form (AF 01-010 see ANNEX 1) to the Research Protocol packages.
- ❖ Keep the copy of the submitted documents with original signatures in the "Submission" file.

5.4 Store the received packages

- ❖ Bind the packages together appropriately.
- ❖ Store the dated and initial original protocol packages on the AAERC submission shelf for review in First in First Out (FIFO) sequence.

6. Glossary

Exempted protocols: Research activities in which the only involvement of human participants will be in one or more of the specific categories stated below can be considered as exempt:

Education: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behaviour, provided the research participants cannot be identified; Research conducted in established or commonly accepted educational settings, involving normal educational practices.

7. ANNEX

ANNEX 1	AF 01-007	Contents of a Submitted Package
ANNEX 2	AF 02-007	Document Receipt Form

8.Reference

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs: SOP# AA 008, 010, 012, 013, 014 and 015.
4. National Health Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014

ANNEX 1 Contents of a Submitted Package
Form AF 01-007

Contents of a Submitted Package

☐ **Initial Review Submitted Package**
- ❑ Protocol Summary Sheet or Memorandum
- ❑ Original Initial Review Application Form
- ❑ Protocol and Protocol-Related Documents

Protocol Number_____

☐ information for subjects ☐ informed consent form
☐ case report forms (CRF) ☐ study budget
☐ investigator's brochure ☐ 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
☐ investigator's brochure ☐ 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.

☐ **Annual Continuing Review Package**
- ❑ Request for Annual Continuing Review Memorandum
- ❑ Original Continuing Review Application Form
- ❑ Current Informed Consent Document (last approved by the AAERC)

☐ **Protocol Termination Package**
- ❑ Request for Termination Memorandum
- ❑ Original Continuing Review Application Form (Termination Submissions are contained on this form).

ANNEX 2 Document Receipt Form
AF 02-007

Document Receipt Form

		Received number:	□□□ / □□ - □□
Protocol Number:		Submitted date:	
Type of Submission:	□ Initial Review □ Resubmission for re-review □ Protocol Amendments	□ Continual Review of Approved Protocols □ Protocol Termination/Final Report	
Protocol Title:			
Principal Investigator:			
Telephone number:		Fax:	
E-mail:		Preferred	□ Phone □ Fax □ e-mail
Institute:			
Delivery route:	□ Post □ E-submission □ in Person		
Documents submitted:	□ Complete □ Incomplete, will submit on……....		
Documents to be submitted later:	□ information for subjects □ informed consent form □ case report forms (CRF) □ study budget □ investigator's brochure □ others……	Check what documents are received later on. □ information for subjects □ informed consent form □ case report forms (CRF) □ study budget □ investigator's brochure □ others……	
Received by:			
Date received:			

Note: *Please bring this receipt with you when contacting the* AAERC.

Table of Contents

1. Purpose

This SOP describes how the AAERC members use the assessment forms when reviewing the study protocols initially submitted for approval. The Assessment Form (AF 01-008) is designed 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 AAERC. 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 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 AAERC 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 and the Scientific Director (if applicable) of AHRI/ALERT 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	AAERC Secretariat
	↓	
2.	Review the Study Protocol	AAERC members
	↓	
3.	Examine qualification of Investigators and study sites	AAERC members
	↓	
4.	Review study participation	AAERC members
	↓	
5.	Examine community involvement and impact	AAERC members
	↓	
6.	Make a decision	AAERC members
	↓	
7.	Gather Assessment Reports	AAERC Secretariat
	↓	
8.	Record the AAERC Decision	AAERC Secretariat

5. Detailed instructions

5.1 Summarize the protocol in an Application Assessment Form.

5.1.1 General Protocol Information

- Record general information about the protocol in the form AF 01-008 (ANNEX 1) such as:
  - Title of the protocol
  - Protocol number and date
  - Principal Investigators, license where applicable & contact number
  - Co-investigators & contact number
  - Funding agency & contact number
  - Study types
  - Duration of the study
  - Status of the protocol – New / Revised / Amended
  - Review status – Regular / Expedited / Emergency
  - Reviewer's name
  - Objective(s) 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.

- A senior named co-investigator should advise student researchers.

5.4 Review study participation

- Voluntary, non-coercive recruitment/participation
- Procedures for obtaining informed consent
- In case of verbal consent, the PI should submit the content of verbal consent in written for review
- 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 (AF 02-008), see ANNEX 2
- Record the decision by marking in the desired block any of the following Approved, Approved with minor revision,

- Approved with major revision, resubmission and disapproved based on the following criteria: -
  - Approval- Studies that do not compromise scientific validity and ethical standards
  - Minor – editorial issues, lack of minor documents (eg. incomplete signature page, minor inconsistency in translation,)
  - Major – major concern in ethical standard (e.g. participant safety, COI) , major concern on study design and methodology,
  - Resubmission – major concern that the study exposes unnecessarily study participants to risk and needs major changes in study design and methodology, concern on the lack of enough safeguards when vulnerable participants are included in the study, major concern on capacity of researcher/s ….
  - Disapproved –major ethical deviation and study design deviation that affects participant's safety
- 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 AAERC 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 SOP # AA 021 Preparation of meeting agenda and minutes.

5.8 Record the AAERC decision.

- Get the AAERC decision form. (AF 03-008), see Annex 3.
- Complete the information. (The Secretariat)
- List participating members and their votes.
- Summarize the guidance, advice and decision reached by the AAERC members.
- Sign and date the document. (The Chairperson of the AAERC or by the
- Scientific Director, where applicable)

- ❖ Make a copy of the completed decision form.
- ❖ Keep the original copy in the file labeled "AAERC decision".
- ❖ Keep the copy of the decision form with the study protocol
- ❖ Return the file and the protocol to the appropriate shelves.

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 subjects	A vulnerable category of subjects 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. ANNEX

ANNEX 1	AF 01-008	Study Assessment Form (5 pages)
ANNEX 2	AF 02-008	Assessment Report Form
ANNEX 3	AF 03-008	AAERC Decision
ANNEX 4	AF 04-008	AAERC Approval Letter

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Ethical Guidelines for Biomedical research on Human Subjects, 2000.
4. Associated SOPs: AA # 021
5. National Health Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014

ANNEX 1 Study Assessment Form

AF 01-008

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Study Assessment Form

Protocol Number:		Date submitted	
Protocol Title:			
Principal Investigator:		License: No:	
Institute**:**		Contact No.	
Co – investigator(s):		Contact No.	
Total No. of Participants:		No. of Study site:	
Funding Agency:		Contact No.	
Duration of the Study:		Status:	☐ New ☐ Revised ☐ Amended
Reviewer's name:		Contact No.	
Type of the Study:	☐ Intervention ☐ Epidemiology ☐ Observation ☐ Document based ☐ Individual based ☐ Genetic ☐ Social Survey ☐ Others, specify……		
Review Status:	☐ Regular ☐ Expedited ☐ Emergency		

Description of the Study in brief: Mark whatever applied to the study.

☐ Randomized	☐ Stratified Randomized	☐ Open-labeled
☐ Double blinded	☐ Placebo controlled	☐ Treatment controlled
☐ Cross-over	☐ Parallel	☐ Interim Analysis
☐ Use of Tissue samples	☐ Use of Blood samples	☐ Use of genetic materials
☐ Multi-center study	☐ Screening	☐ Descriptive

Brief the study design and the statistic used:

Study objectives_____

_____

_____

_____

ANNEX 1
AF 01-008
Page 2 of 6

1	Objectives of the Study ☐ Clear ☐ Unclear	What should be improved?
2	Need for Human Participants ☐ Yes ☐ No	Comment:
3	Methodology: ☐ Clear ☐ Unclear	What should be improved?
4	Background Information and Data ☐ Sufficient ☐ Insufficient	Comment:
5	Risks and Benefits Assessment ☐ Acceptable ☐ Unacceptable	
6	Inclusion Criteria ☐ Appropriate ☐ Inappropriate	Comment:
7	Exclusion Criteria ☐ Appropriate ☐ Inappropriate	Comment:
8	Withdrawal Criteria ☐ Appropriate ☐ Inappropriate	Comment:
9	Involvement of Vulnerable Participants ☐ Yes ☐ No	Comment:
10	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No	Comment:
11	Sufficient number of participants? ☐ Yes ☐ No	Comment:
12	Control Arms (placebo, if any) ☐ Yes ☐ No	Comment:

ANNEX 1
Form AF 01-008
Page 3 of 6

13	Are Qualification and experience of the Participating Investigators appropriate? ☐ Yes ☐ No	Comment:
14	Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
15	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate	Comment:
16	Community Consultation ☐ Yes ☐ No	Comment:
17	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and Publication of Results ☐ Yes ☐ No	Comment:
18	Contribution to Development of Local Capacity for Research and Treatment ☐ Yes ☐ No	Comment:
19	Benefit to Local Communities ☐ Yes ☐ No	Comment:
20	Availability of similar Study / Results ☐ Yes ☐ No	Comment:
21	Are blood/tissue samples sent abroad? ☐ Yes ☐ No	Comment:

ANNEX
Form AF 01-008
Page 4 of 6

22	Does the study involve sample storage? If 'No', go to # 27 ☐ Yes ☐ No	Comment:
23	Is the duration of specimen storage specified? ☐ Yes ☐ No	Comment:
24	Separate consent for specimen storage sought ☐ Yes ☐ No	Comment:
25	Planned practice for storage, coding and further utilization of stored specimens ☐ Appropriate ☐ Inappropriate	Comment:
26	Institutional support/permit confirming adequate samples storage commitment for long term storage sought ☐ Yes ☐ No	Comment:
27	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	Comment:
28	Contents of the Informed Consent Document ☐ Clear ☐ Unclear	Comment:
29	Language of the Informed Consent Document ☐ Clear ☐ Unclear	Comment:
30	Contact Persons for Participants ☐ Yes ☐ No	Comment:
31	Privacy & Confidentiality ☐ Yes ☐ No	Comment:

ANNEX 1

32	Inducement for Participation ☐ Unlikely ☐ Likely	Comment:
33	Provision for Medical / Psychosocial Support ☐ Appropriate ☐ Inappropriate	Comment:
34	Provision for Treatment of Study-Related Injuries ☐ Appropriate ☐ Inappropriate	Comment:
35	Provision for Compensation ☐ Appropriate ☐ Inappropriate	Comment:

Review Date Protocol number:

Protocol Title:		
Elements Reviewed (AA 01-008)	☐ Attached ☐ Not attached	
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
DECISION:	☐ Approved ☐ Approved with minor revisions ☐ Approved with major revisions ☐ Resubmission ☐ Disapproved	
Comment:		
Signature:		Date:

ANNEX 3 AERC Decision
Form AF 03-008

Meeting No_____/_____ Date (D/M/Y):_____
Protocol number_____

Protocol Title:		
Principal Investigators:		
Institute:		
Type of Review	☐ Initial Review ☐ Resubmission ☐ Amendments ☐ Continual Review ☐ Protocol Termination/Final Report	
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
Protocol Version Date: ……/…../……..	ICF Version Date: ……/…../……..	
DECISION OF THE MEETING:	☐ Approved ☐ Approved with minor revisions ☐ Approved with major revisions ☐ Resubmission ☐ Disapproved	
APPROVAL PERIOD	……/…../…….. to ……/…../……..	
Progress Report Expected	☐ 3 Months ☐ 6 Months ☐ 9 Months ☐ 1 Year	

The PI's responsibilities include submission to the IRB of any amendments or deviations from the protocol, SAE report, Progress report on the expected due date, and end of study report.

Chairperson
Name:_____
Signature:_____
Date:_____

Scientific Director, AHRI
Name:_____
Signature_____
Date_____

ANNEX 4 AAERC approval letter
Form AF-04-008

AAERC approval letter

Protocol number_____

Protocol Title:_____

Investigators:_____

Study Site_____

Decision of the meeting: ☐ Approved

I. Elements approved- 1. Protocol Version No_____
2. Protocol Version Date_____
3. Informed consent Version No._____
4. Informed Consent 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 AAERC approval
3. The PI should report SAE within 10 days of the event
4. End of the study, including manuscripts and thesis works should be reported to the AAERC

AAERC Approval date: _____

Approval period from _____ to_____

☐ NRERC (if the protocol should go to National ERC)

Follow up report expected in …...

3 Months _____ 6 Months _____ 9 Months _____ One year_____

Name: _____ _____ _____

Signature: _____ _____ _____

Date: _____ _____ _____

AAERC Chairperson AAERC Secretary AHRI Scientific Director

Table Of Contents

1. Purpose

The purpose of this SOP is to provide criteria for determination of which study protocols can be reviewed through expedited process as well as instructions on management, review, and approval of the **expedited** review

2. Scope

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes of currently approved studies.

3. Responsibility

It is the responsibility of the AAERC secretariat to define of which study protocols should be reviewed and approved through expedited channel.

4. Flow chart

No.	Activity	Responsibility
1.	Receive the submitted documents	AAERC Secretariat
2.	Determine protocols for expedited review	AAERC Secretariat/ Chairperson
3.	Expedite process	AAERC Secretariat/ Chairperson
4.	Communicate with the AAERC and the Investigator	AAERC Secretariat Members

5. Detailed instructions

5.1. Receive the submitted documents.

- Receive the application documents submitted by investigators.
- Get contents of submitted package (checklist) form, AF 01-007 (see Annex 1 of SOP# AA 007), to 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 AAERC secretariat.

5.2. Determine protocols for expedited review.

- ❖ AAERC secretariat determines whether a study is qualified for expedited review according to the following criteria:

5.2.1. Modification /amendment of protocol

- ❖ administrative revisions, such as correction of types
- ❖ 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.

5.2.2. 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.

5.2.3. Social Science research / proposals that does not involve vulnerable subjects like commercial sex works, prisoners and disadvantaged communities

5.2.4. Protocols that do not deviate from societal and cultural values

5.2.5. Protocol that do not involve genetic studies

5.2.6. Social science studies, which may not pose psychosocial impact such as depression, stress, anxiety, (even though they may not cause physical harm)

5.2.7. 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).

5.2.8. 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 NO recommended for expedited review.

5.2.9. Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.

5.2.10. Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and no additional risks have been identified.

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

5.3. Expedited Process

- Chairperson nominates 2 or more AAERC members to review the revised protocol.
- The selected members are normally those who reviewed and recommended the previous version of that protocol, if it is not submitted for the first time.
- The secretariat sends the revised protocol to the selected members.
- Carry out the expedited review on the complete proposal (study protocol with all the attached documents as mentioned in the guidelines for submission of proposals - see AAERC GL 02).
- The review may be made either by circulation of comments, telephone discussion or meeting.
- The reviewers will have ten days to review and communicate their decision to secretariat
- The secretariat will have five days for communication with the reviewers and the PI
- If consensus cannot be reached, the chairperson will refer the proposal back to the AAERC for a full review
- The expedited review should not take longer than 2 weeks
- Inform the AAERC of the proposals approved by expedited review at its regular meetings.
- If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review.

5.4. Communicate with the AAERC and the investigator.

- The reviewers forward their comments to the Secretariat.

- ❖ Full Board notification of items approved through expedited review by the Chairperson, or the designee is accomplished by providing notification and source documentation of the items in the meeting agenda / notes.
- ❖ The AAERC Secretariat communicates the decision to the investigator.

6. Glossary

Administrative Documents	Documents include official minutes of Board meetings as described in Standard Operating Procedures, both historical and Master Files as described in SOP# AA 026
Expedited approval	An AAERC approval granted only by the Chairman of the AAERC or a designated AAERC member (not the full Committee) for minor changes to current AAERC approved research activities and for research which involves no more than minimal risk.
Expedited review	A review process by only two or more designated AAERC 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*.

7. ANNEX: none

8. Reference

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. Committees
2. International Conference on Harmonization, Guidance on Good Practice (ICH GCP) 1996. Clinical
3. Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April 2003, Food and Drug Administration, U.S. Government PrintingOffice via GPO Access.
4. Related SOPs: # AA 007 and AA 027; AAERC GL 02

Table Of Contents

1.Purpose

This standard operating procedure describes how the AHRI ALERT Ethics Review committee (AAERC) manages to review an initially submitted protocol.

2.Scope

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

3.Responsibility

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

The AAERC Secretariat is responsible for receiving, verifying, and managing the contents of both the hard copies and the electronic version of the received packages.

In addition, the secretariat should create a protocol specific file, distribute the packages, and get them reviewed by the AAERC and deliver the review results to the applicants.

4.Flow chart

No.	Activity	Responsibility
1.	Receive the distributed protocol package	AAERC Members/Reviewer
	↓	
2.	Verify the contents of the package	AAERC Members/Reviewer
	↓	
3.	Review the protocol	AAERC Members / Reviewers
	↓	
4.	Discuss in an AAERC meeting	AAERC Members / Reviewers / Secretariat / Chairperson
	↓	
5.	Preliminary Communication of the Decision	AAERC Secretariat /Chairperson
	↓	
6.	Final Communication of the Decision	AAERC Members / Chairperson
	↓	
7.	Storage of the Documents	AAERC Secretariat

5.Detailed instructions

5.1. Receive the distributed protocol packages

- Check the distributed packages.
- Sign and date an acknowledgement form upon receiving the packages.
- Return the receipt form back to the delivery person / AAERC secretariat.

5.2. Verify the contents of the package

- Look for an Assessment Form.
- Look for the due date for the review.
- Check the meeting date to see if the investigator is available to attend the meeting.
- Notify the AAERC Secretariat if there are documents missing, or the specified date cannot be met.

5.3. Review the Protocol

5.3.1. Initial Review Application Form

- Check the form for completeness of the information and signatures of the principal investigator, the protocol chairperson (if applicable), the AAERC Chairperson and Secretariat.
- Check and attach the Initial Review Application Form (AA 01-010 see ANNEX 1) to the Research Protocol.

5.3.2. Assessment Form

- Use the Assessment Form (AA 01-008 in SOP# AA008) to guide the review and deliberation process.

  Note: The completed Assessment Form is the official record of the decision reached by the AAERC for the specific protocol.
- Consider the following criteria when performing the review:
  - minimize risks to participants;
  - risks must be reasonable in relation to anticipated benefits;
  - participants are selected equitably;
  - informed consents adequate, easy to understand and properly documented.

- If waiver of consent is requested, check if it fulfills the criteria (see under 5.3.3)
- the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
- there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate; and
- appropriate safeguards are included to protect vulnerable participants.

❖ Make comments where appropriate.

❖ Sign and date the reviewer's name.

5.3.3. Waiver of informed consent

If the IRB determines:

❖ The research project carries no more than minimal risk

❖ The research project could not practically be carried out without the waiver or alteration

❖ In emergency conditions of national or regional importance, for example epidemics, where a participant cannot refuse informed consent

❖ In situations where deception needs to be applied to achieve the objectives of the study (eg. in Social Science research)

❖ The only record linking the research participant and the research project would be the consent document and the principal risk to the research participant would be potential harm resulting from a breach of confidentiality (eg. in social science research).

5.4. **AAERC meeting**

❖ The primary reviewer presents a brief oral or written summary of the study design and his/her comments. When required, the AAERC may invite investigators to explain protocols.

❖ The Chairperson or designee entertains discussion on each document under consideration (e.g., protocol, informed consent, investigators and site qualifications, advertisements).

- Recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes as 'with modifications made by AAERC and will be communicated to the investigator.
- The Chairperson or designee calls for a separate vote on each element in review. The Committee votes to either:
  - Approve the study to start as presented with no modifications.
  - Approve the study to start with Committee approved modifications to the consent, secretariat will check the fulfillment required. = *Approved with minor recommendation*
  - Require modifications to items noted at the convened meeting and follow-up by the Chairperson and selected members of the committee based on area of expertise, after receipt of the requested modifications. = *Approved with major recommendation*

    Protocols falling to this decision category may involve major concerns in ethical standard such as participant safety, COI, study design and methodology
  - Require modifications to the items and full Committee review of the materials = Resubmission

    Protocols falling to this decision category may involve major concerns that the study exposes study participants unnecessarily to risk and needs major changes in study design and methodology, concern on the lack of enough safeguards when vulnerable participants are included in the study, major concern on capacity of researcher/s, or available infrastructures….
  - Not approve the study, stating the reason for disapproval = Disapproved
- When required, the AAERC may invite investigators to explain protocols.
- If the study is approved, the Committee determines the frequency of Continuing Review from each investigator.
  - The Secretariat sends an action letter along with the approved documents to the investigator.

- The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- An approval and expiration date is placed on every page of each consent form approved by the AAERC

- If the Committee votes not to approve the study, the Secretariat immediately notifies the investigator in writing about the decision and the reason for not approving the study.
  - If the investigator wishes to appeal to the decision, he/she may do so by contacting the AAERC Secretariat. The appeal process is stated in the action letter to the investigator.
- If the Committee requires modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the AAERC.

5.5. **Final Communication of the Decision**

5.5.1. Signature of Approval

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

5.5.2. The Assessment Form

- Complete the Assessment Form.
- Get signature of the Chairperson.
- Maintain the completed Assessment Form and the minutes of the meeting relevant to the protocol review.
- Process the above tasks within 5 working days after the meeting.

5.5.3. The Application Review Form

- Get the Chairperson to sign and date the original version of this form within 5 working days and return this to the Secretariat.
- Assign the AAERC number at the bottom boxes on the last page of the Form (AF 01-010) by filling in the boxes with numbers in sequential order, "□□□/□□-□□"; the approval sequence in the first three boxes, the current month after the slash and the current year after the dash sign.

  Example: A protocol, submitted in November of the year 2002 and it is the 12th protocol approved by the AAERC in that year, would be numbered as AAERC 012/11-02.
- Sign and date the form by the Secretariat.

5.5.4. The Action Letter

- Decision of meeting will be communicated to the PI within seven days of review in the form of comments/recommendations. The Decision form will be kept in the protocol file (see SOP# AA 021).
- State clearly the actions that need to be taken by the investigator.
- For the decision disapproval, a notifying letter to the investigator or the project manager should state the followings:
- "If you wish to appeal to this decision, please contact the AAERC and submit your appeal in writing, addressed to the AAERC Chairperson with justification as to why the appeal should be granted"
- Verify the correctness of the wordings and spelling.

5.6. **Storage of the Documents**

- Keep a copy of the Action Letter in the Correspondence file.
- Place the original documents of the Application Review and the Assessment Forms in sequence of approval number in the Approved file.
- Store the file on an appropriate shelf in the designated cabinet.

6. Glossary

Initial Review	The first-time review of a protocol made by two or three

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

7.ANNEX

ANNEX 1 AF 01-010: **Application Form** for Initial **Review** (2 pages)

8.References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs: SOP# AA 010, AA 021

Annex 1 Application Form for Initial Review

Form AF 01-010
Page 1 of 2

Application Form for Initial Review

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

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

☐ Survey ☐ Social ☐ Medical ☐ Community based ☐ Individual based
☐ Screening ☐ Observational ☐ Epidemiology ☐ Intervention study
☐ Clinical Trial ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
☐ Genetic Study ☐ Retrospective ☐ Prospective ☐ Others…… STUDY

POPULATION: ☐ Healthy ☐ Patient ☐ Vulnerable groups

CHARACTERISTICS of PARTICIPANTS PARTICIPATED:

Age Range: ☐ 0 -17 yrs ☐ 18 - 44 yrs ☐ 45 - 65 yrs ☐ ≥ 66 yrs
Pediatric ☐ None ☐ < 1 yr ☐ 1-3 yrs ☐ 4 -14 yrs
Impaired ☐ one ☐ Physically ☐ Cognitively ☐ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:

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

SPECIAL RESOURCE REQUIREMENTS (check all that apply):

☐ Intensive Care ☐ Isolation unit ☐ Surgery
☐ Pediatric Intensive Care ☐ Transfusion ☐ CAT scan
☐ Gene therapy ☐ Controlled substances (Narcotics/Psychotropics)
☐ Prosthetics ☐ Gynecological services ☐ None
☐ Others, specify_____ ☐ Organ transplantation, specify_____

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

☐ None ☐ Medically indicated only

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

☐ None
☐ IND
DACA No_____
Name:_____
_____
Sponsor
☐ IDE
DACA No:_____
Name:_____
Sponsor:_____
Holder:

PROCEDURE USE: ☐ Invasive ☐ Non-invasive
MULTI-SITE ☐ YES ☐ NO
FINANCIAL ☐ YES ☐ NO

APPLICANT INSTITUTE RESEARCH CONTACT

Name:_____
Address:
Telephone:_____
Fax:_____
E-mail:_____

ANNEX 1
Form AF 01-010
Page 2 of 2

Application Form For Initial Review

Participating Investigators:

First / Last Name	License No.	Institution	Telephone / Fax No.
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

TYPE OF REVIEW:

☐ Initial Review	☐ Emergency Review
☐ Resubmission Review	☐ Continuing Review
☐ Amendment Review	☐ Report Review
☐ Expedited Review	☐ Protocol Termination

I declare that all the required documents (as per the AAERC check list) are submitted along with my proposal and will take the responsibility for delays incurred in the review process, if failed to do so.

SIGNATURES:

_____ Date: _____
Principal Investigators

_____ Date: _____
Protocol Chairperson (if applicable)

COMPLETION:

_____ Date: _____
Secretary, AAERC

APPLICATION NUMBER: ☐☐☐ / ☐☐ - ☐☐

Table Of Contents

1. Purpose

The purpose of this procedure is to provide instructions for review and approval of medical device studies submitted to the AAERC.

2. Scope

This SOP applies to the submission and the review processes of protocols involving the study of new medical devices in human subjects.

3. Responsibility

During the review of medical device studies, the AAERC may make some different decision than those made during the review of drug studies. The AAERC must determine if the proposed investigation has Significant Risk (SR) or Non-significant Risk (NSR), and then the AAERC should decide if the investigation is approved or not. In determining SR or NSR, the AAERC must review all information submitted by the sponsor.

The AAERC should consider the nature of the harm that may result from the use of the device. If a device being investigated might cause significant harm to any one of the participants, the study will be considered SR. In deciding if a device presents significant or non-significant risks, the AAERC should consider the device's total risks, not those compared with the risks of alternative devices or procedures. If the device is used in conjunction with a procedure involving risk, the AAERC should consider the risks of the procedure in conjunction with the risks of the device. The AAERC may also consult with the regulatory agency to form its opinion.

The AAERC may agree or disagree with the sponsor's initial NSR assessment. If the AAERC agrees with the sponsor's initial NSR assessment and approves the study, the study may begin without submission of an IDE (Investigational Device Exemption) application to the regulatory agency. If the AAERC disagrees, the sponsor must notify the regulatory agency that an SR determination has been made. The study can be conducted as an SR investigation following regulatory approval of an IDE application.

4. Flow chart

No.	Activity	Responsibility
1.	Submission of documents	Applicant/AAERC Secretariat
	↓	
2.	Activities before AAERC meeting	AAERC Secretariat / members / Reviewers
	↓	
3.	Activities during AAERC meeting	AAERC members / Secretariat / Chairperson
	↓	
4.	Activities after the meeting	AAERC Secretariat
	↓	
5.	Notify the investigators	AAERC Secretariat
	↓	
6.	Storage of the documents	AAERC Secretariat

5. Detailed instructions

5.1. Submission of documents

- At a minimum, the AAERC must receive the following documents prior to review/approval of a medical device study:
  - Proposed investigational plan
  - Informed consent form
  - Description of the device
  - Description of participant selection criteria
  - Monitoring procedures
  - Reports of prior investigations conducted with the device
  - Investigator's Curriculum Vitae
  - Investigator's professional license (s)
  - Risk assessment data / information
  - Statistics used in making the risk determination.
  - Application for Review (AA 01-010)
  - Document Received Form (AF 02-007)
  - Copies of all labeling for investigational use only
- The sponsor should inform the AAERC whether other ERC have reviewed the proposed study and what determination was made.

- ❖ The sponsor should inform the AAERC of the Agency's assessment of the device's risk if such an assessment has been made.
- ❖ If the Sponsor believes the study is NSR, supporting information must be submitted.
  - ➢ Contact the applicant to submit additional information or documents, if the application is complete.

5.2. Before the AAERC meeting

- ❖ Assign two primary reviewers to review the study, according to the assessment form (see SOP# AA 008).
- ❖ Prepare the documents for distribution to each AAERC member.
- ❖ Send the documents to each AAERC member.
- ❖ Place the new medical device study on the meeting agenda.

5.3. During the AAERC meeting

- ❖ The two primary reviewers present a brief oral or written summary of the study design.
- ❖ The Chairperson opens discussion about whether the study is SR or NSR (see examples in ANNEX 1, AA 01-011).
- ❖ The Chairperson leads discussion about each document under consideration (e.g. protocol, informed consent, investigators and site qualifications, advertisements).
- ❖ Decide the degree of risk.
- ❖ Consider whether or not the study should be approved.
- ❖ The Chairperson calls for a separate vote on each element in review. The AAERC votes to either:
  - ➢ Approve the study to start as presented with no modifications
  - ➢ Approve the study to start with minor modifications to item(s) noted at the convened meeting and to be followed-up by the Secretariat and Chairperson, after receiving the requested modifications
  - ➢ Require major modifications and/or request further information to be resubmitted and subjected to review in the next full Board meeting.
  - ➢ Disapprove the study and state the reason.

- ❖ Record the vote of risk assessment in the decision form (AF 02-008) and the meeting minutes (AA 02-021).
- ❖ Note the recommendations for changes to the protocol and/or informed consent recommended by AAERC members in the minutes as 'with modifications made by AHRI/ALERT and will be communicated to the investigator.
- ❖ Determine the frequency of Continuing Review for the approved study.

5.4. After the AAERC meeting

5.4.1. Prepare meeting minutes

- ❖ Follow the procedure in SOP# AA 021.

5.4.2. Notify the investigators

- ❖ The Secretariat sends an action letter along with the approved documents to the investigator. The letter contains, at a minimum, a listing of each document approved, the date set by the AAERC for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- ❖ If the AAERC votes not to approve the study, the Chairperson or Secretariat immediately notifies the investigator in writing of the decision and the reason for disapproving the study. If the investigator wishes to appeal this decision, he or she may do so by contacting AAERC. This process is stated in the action letter provided to the investigator.
- ❖ If the AAERC votes to require modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the AAERC.
- ❖ Storage of the documents
- ❖ Prepare an appropriate label.
- ❖ Store the document packages in the shelf for active files.

6. Glossary

Medical Device	Any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis of disease and other conditions (for example, pregnancy).
Investigational Medical Device	A medical device which is the object of clinical research to determine its safety or effectiveness.
Investigational Device Exemption (IDE)	Investigational Device Exemption allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Pre-market Approval (PMA) application or a Pre-market Notification submission to the regulatory agency. Clinical studies are most often conducted to support a PMA. Only a small percentage of studies require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. An IDE is approved by AAERC. If the study involves a significant risk device, the IDE must also be approved by the regulatory agency. An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements that would apply to devices in commercial distribution. Sponsors need not submit a PMA (Pre-Market Approval) or Pre-market Notification, register their establishment,

	or list the device while the device is under investigation. Sponsors of IDE's are also exempt from the Quality System (QS) Regulation except for the requirements for design control.
New Study	A study protocol including the informed consent, investigator qualifications, and advertisements presented to the AAERC for approval for the first time. This includes re- application for those studies denied approval by AAERC.
Non-significant Risk Device (NSR)	An investigational device that does not pose a significant risk. A list of examples is found in ANNEX 1.
Risk	The probability of harm or discomfort to study participants. Acceptable risk differs depending on the conditions for which the product is being tested. A product for sore throat, for example, will be expected to have a low incidence of side effects. However, unpleasant side effects may be an acceptable risk when testing a promising treatment for a life- threatening illness.
Significant Risk Device (SR)	An investigational device that: 1. is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the participant, 2. (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the participant, 3. (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the participant, or 4. (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participant. A list of examples is found in ANNEX 2.

7. ANNEX

ANNEX 1 Examples of Non-significant Risk Device Studies

ANNEX 2 Examples of Significant Risk Device Studies

8. References

1. Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April2003, Food and Drug Administration, U.S. Government Printing Office via GPO Access
2. Related SOPs: SOP# AA 007-010 and 021

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ANNEX 1 NON-SIGNIFICANT RISK DEVICE STUDIES

Page 1 of 1

NON-SIGNIFICANT RISK DEVICE STUDIES

EXAMPLES:

- Bio-stimulation Lasers for treatment of pain
- Caries Removal Solution
- Daily Wear Contact Lenses and Associated Cleaners and Solutions
- Dental Filling Materials, Cushions or Pads made from traditional materials and designs
- Denture Repair Kits and Re-aligners
- Gynecologic Laparoscope and Accessories at power levels established prior to May 28, 1976 (excluding use in female sterilization)
- Externally worn Monitor for Insulin Reactions
- Jaundice Monitor for Infants
- Magnetic Resonance Imaging (MRI) Devices within specified physical parameters
- Menstrual Pads
- Menstrual Tampons of "old" materials (used prior to May 28, 1976)
- Non-implantable Male Reproductive Aids
- Ob/Gyn Diagnostic Ultrasound (within specified parameters)
- Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain
- Wound Dressings, excluding absorbable hemostatic devices and dressings

ANNEX 2 SIGNIFICANT RISK DEVICE STUDIES
Page 1 of 3

Significant Risk Device Studies

General Medical Use

Catheters:

- Cardiology – diagnostic, treatment, transluminal coronary angioplasty, intra- aortic balloon with control system
- Gastroenterology and Urology – biliary and urologic
- General Hospital – long-term percutaneous, implanted, subcutaneous and intravascular
- Neurology – cerebrovascular, occlusion balloon
- Collagen Implant Material for use in ear, nose and throat, orthopedics and plastic surgery
- Lasers for use in Obstetrics/ Gynecology, cardiology, gastro-enterology, urology, pulmonary, ophthalmology and neurology
- Tissue Adhesives for use in neurology, gastro-enterology, ophthalmology, general and plastic surgery, and cardiology

Anesthesiology

- Respiratory Ventilators
- Electro-anesthesia Apparatus
- Gas Machines for Anesthesia or Analgesia
- High Frequency Jet Ventilators greater than 150 BPM

Cardiovascular

- Arterial Embolization Device
- Artificial Heart, permanent implant and short-term use
- Cardiac Bypass Systems: oxygenator, cardiopulmonary blood pump, ventricular assist devices
- Cardiac Pacemaker/Pulse Generator: implantable, external transcutaneous, ant tachycardia, esophageal
- Cardiovascular/Intravascular Filters
- Coronary Artery Retro Perfusion System
- DC-Defibrillators

ANNEX 2

- Implantable Cardioverters
- Laser Coronary Angioplasty Device
- Pacemaker Programmer
- Percutaneous Conduction Tissue Ablation Electrode
- Replacement Heart Valve
- Vascular and Arterial Graft Prostheses

Dental

- Endosseous Implant

Ear, Nose and Throat

- Cochlear Implant
- Total Ossicular Prosthesis Replacement
- Gastroenterology and Urology
- Anastomosis Device
- Endoscope and/or Accessories
- Extracorporeal Hyperthermia System
- Extracorporeal photopheresis System
- Extracorporeal Shock-Wave Lithotriptor
- Kidney Perfusion System
- Mechanical/Hydraulic Impotence and Incontinence Devices
- Implantable Penile Prosthesis
- Peritoneal Shunt

General and Plastic Surgery

- Absorbable Haemostatic Agents
- Artificial Skin
- Injectable Silicone
- Implantable Prostheses: chin, nose, cheek, ear
- Sutures
- Endoprostheses

ANNEX 2

Page 3 of 3

General Hospital

- Infusion Pumps: Implantable and closed loop, depending on infused drug
- Implantable Vascular Access Devices

Neurology

- Hydrocephalus Shunts
- Implanted Intracerebral / Subcortical Stimulator
- Implanted Intracranial Pressure Monitor
- Implanted Spinal Cord and Nerve Stimulators and Electrodes

Obstetrics and Gynecology

- Cervical Dilator
- Chorionic Villus Sampling Catheter, phase II (pregnancy continued to term)
- Contraceptive Devices: tubal occlusion, cervical cap, diaphragm, intrauterine device (IUD) and introducer, and sponge

Ophthalmics

- Extended Wear Contacts Lens
- Intraocular Lens (investigations subject to 21 CFR 813)
- Eye Valve Implant
- Retinal Reattachment Systems: sulfur hexafluoride, silicone oil, tacks, perfluoropropane

Orthopedics

- Implantable Prostheses: ligament, tendon, hip, knee, finger
- Bone Growth Stimulator
- Calcium Tri-Phosphate/Hydroxyapatite Ceramics
- Xenografts

Radiology

- Hyperthermia Systems and Applicators

Table Of Contents

1.Purpose

The purpose of this procedure is to describe how protocol amendments are managed and reviewed by the AAERC.

2.Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval by the AAERC. Amendments made to protocols may not be implemented until reviewed and approved by the AAERC.

3.Responsibility

It is the responsibility of the AAERC Secretariat to manage protocol amendments. Investigators may amend the contents of protocols from time to time. Protocol amendments may be submitted for either "expedited" review by the Chairperson / Secretariat/members / reviewers or full AAERC review.

4.Flow chart

No.	Activity	Responsibility
1.	Manage the Amendment Package	AAERC Secretariat
2.	Notify the Chairperson of the AAERC	AAERC Secretariat
3.	Determine whether Expedited or Full Review	AAERC Secretariat/ Chairperson
4.	Expedited Review	AAERC Secretariat/ Chairperson
5.	Full Board Review	AAERC Secretariat / members / Chairperson
6.	Amendment Review Process	AAERC Secretariat / members / Chairperson
7.	Notify the Principal Investigator	AAERC Secretariat
8.	Store Documents	AAERC Secretariat

5.Detailed instructions

5.1.Manage the Amendment Package.

- The amendment package is prepared by the PI.

- Upon receipt of the amendment package, the Secretariat of the AAERC should follow the receiving procedure in SOP# AA 007 (Management of Protocol Submission) and SOP# AA 024 - Procedure for Maintaining Confidentiality of AAERC Documents.
- **Request for Amendment Memorandum** of the Protocol by the Principal Investigator on an existing and previously approved protocol. The memorandum should:
  - State/describe the amendment
  - Provide the reason for the amendment
  - State any untoward effects with original protocol
  - State expected untoward effects because of the amendment
- **Original Amendment Submission Form**
  - Check for completeness and for the presence of the required signatures (Principal Investigator or Medical Advisor of the Institute, if applicable). See ANNEX 1 on page 9.
- **Protocol and Related Documents**
  - The amended version of the protocol and related documents should be provided.
  - The changes or modifications should be underlined or highlighted.

5.2. Notify the Chairperson of the AAERC.

- Upon receipt of the amendment package, the Secretariat should inform the Chairperson of the AAERC verbally or in writing.
- Keep "Sent" and "Received" mail related to the notification of the Chairperson in the protocol file under the Correspondence section.
- Send the request for amendment memorandum and the protocol and related documents to the Chairperson within one working day of receipt by the Secretariat.
- Follow AAERC SOP# AA 001 in preparing and distributing the documents.
- After review of the materials, the Chairperson will determine whether the protocol requires expedited or full review.

5.3. Determine whether expedited or full review.

- Refer to SOP# AA 009 for Expedited Review.
- Refer to SOP# AA 010 for Full Review.
- Protocol amendment which increase risk to study participants, as judged by the Chairperson, such as a change in study design, which may include but is not limited to:
  - additional treatments or the deletion of treatments
  - any changes in inclusion/exclusion criteria
  - change in method of dosage formulation, such as, oral changed to intravenous
  - significant change in the number of subjects (Increase: if there are <20 subjects enrolled, change of 5 is significant if there are >20 subjects enrolled, a change of 20% is significant – Decrease: if the decrease in the number of subjects alters the fundamental characteristics of the study, it is significant)
  - significant decrease or increase in dosage amount
- If the Chairperson decides the protocol requires full AAERC approval, the Chairperson will indicate this decision on the Checklist, sign and date the form.
- The Secretariat places the protocol amendment request on the agenda for the next convened meeting.
- The following documents are distributed to each AAERC member:
- the amendment's revision documents to clearly identify each change.
- requested changes to the consent form, if applicable
- If an amendment is received just prior to the AAERC meeting, the Chairperson may decide to review the amendment in full AAERC, even though the amendment may be expedited.

5.4. Expedited Review

- Refer to SOP# AA 009 for expedited review procedure.

5.5. Full Review by the AAERC

- Refer to SOP# AA 010 for full Board Review.
- See section 5.6

5.6. Protocol Amendment Review Process

5.6.1. Review amended protocols

- Use the process outlined in the Application Assessment Form (see AAERC SOP# AA 008) to review amended protocols and protocol-related documents.
- Note recommendations for changes to the protocol and/or informed consent requested by AAERC Members in the minutes as "with modifications made by the AAERC and will be communicated to the clinical trial office or investigator.
- The Chairperson or designee calls for a vote on the proposed amendment to:
  - Approve the protocol amendment as is with no modification of the informed consent
  - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with follow-up by the Chairperson
  - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with follow-up by the Chairperson
  - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full AAERC review
  - Suspend the study, until further information is obtained
  - Not suspend the study as currently approved, but request further information regarding the amendment and the effects of the amendments on the approved study
  - Not approve the amendment request, stating the reason – but allow the study to continue as previously approved
- If the AAERC approves the protocol amendment, the Secretariat staff communicates this decision to the investigator.
- If the AAERC does not approve the protocol amendment, the Chairperson Immediately notifies the investigator in writing of the decision and the reason for not approving the amendment.

- ❖ If the AAERC votes to require modifications to any of the documents, or the protocol amendment, the Secretariat sends a written request about the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the AAERC
- ❖ The Chairperson completes a decision form (AA 02-008) after the AAERC has reached its decision.
- ❖ Keep the forms, minutes of the meeting relevant to the discussion and the decision reached by the AAERC as the official records of the amendment review process.

5.6.2. Verbal Communication of the Decision

The Chairperson notifies the Principal Investigator verbally after the AAERC meeting and in writing as soon as possible, but no later than 7 working days following the review.

5.6.3. Preliminary Written Communication of the Decision

The Chairperson must send an electronic version or fax a copy of the Amendment Submission Form with his/her signature and date of approval to the Secretariat in three working days or whenever possible, but no later than seven working days after the review has taken place.

5.6.4. Completion of the Amendment Submission Form

- ❖ The Chairperson must sign and date the original version of this form and return this to the Secretariat no later than 5 working days after the review.
- ❖ Addition of Amendment to the Protocol Number
- ❖ The Secretariat assigns a letter to the protocol number that corresponds to the number of the amendment. For example:
- ❖ The third amendment to the AAERC would be formatted as: AAERC 015/01-03
- ❖ Record the amended protocol number on the form.
- ❖ The Secretariat signs and dates the original version of the form.

5.7. Notify the Principal Investigator.

- ❖ Send a signed and dated Amendment Submission Form to the Principal Investigator (P.I.) for their records no later than 7 working days.

- The Clinical Trials Office or the P.I. Should then provide a "clean" copy (underlining and highlighting removed) of the protocol and related documents as well as the "clean" electronic version (where applicable) to the Secretariat of the AAERC.

5.8. Store documents.

- Place the original completed documents, the "clean" version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

6. Glossary

Amendment protocol package	A package of the amended parts and related documents of the protocol, previously approved by the AAERC. In the course of the study, the PI may decide to make changes in the protocol.
Clinical trial office	an institute or an office where the study takes place and where the principal investigator and/or his/her staff may be reached.
Expedited approval	An AAERC approval granted only by the Chairperson of the AAERC or a designated AAERC member (not the full AAERC) for minor changes to current AAERC approved research activities and for research which involves no more than minimal risk, as stated in the SOP# AA 009.

7. ANNEX

ANNEX 1 AF 01-012 Protocol Amendment Submission Form

8.References

1) World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000
2) International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3) Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April 2003, Food and Drug Administration, U.S. Government Printing Office GPO
4) Access Relevant SOPs: SOP# AA 007, 008, 009, 010 and 024
5) National Health Research Ethics Review Guideline. Addis Ababa, Ethiopia. 4thedition revised in June 2005

ANNEX 1 Protocol Amendment Submission Form Form AF 01-012

Protocol Amendment Submission Form

PROTOCOL NUMBER:	SUBMITTED DATE:
PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	
INSTITUTE:	Telephone:
APPROVED DATE:	NO. OF AMENDMENT:
REASON FOR THE AMENDMENT:	

TYPE OF AMENDMENT REQUESTED:

a) EXPEDITED (Minor changes)

b) FULL REVIEW BY AAERC (More than minor changes or that amendment "materially affects risks to subjects")

_____ Date:_____

SIGNATURES:
Principal Investigator

COMMENTS: ☐ EXPEDITED (Minor changes) ☐ FULL REVIEWED

APPROVALS

_____ _____
Chairperson, AAERC Date

COMPLETION

_____ _____
Secretary, AAERC Date

PROTOCOL NUMBER: AAERC ☐☐☐/☐☐-☐☐

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1. Purpose

This procedure describes how resubmitted study protocols are managed, re-reviewed and approved by the AAERC.

2. Scope

This SOP applies to study protocols that have been reviewed earlier with recommendations from AAERC for some corrections in the initial review process.

3. Responsibility

It is the responsibility of the AAERC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the AAERC for reconsideration.

A re-submitted protocol may be reviewed and approved by either the Chairperson or some AAERC members/reviewers, or full AAERC. How the protocol will be reviewed should have been determined by the AAERC at the time of the initial review. This information can be found on the Decision Section of the Assessment Form.

4. Flow chart

No.	Activity	Responsibility
1.	Receive protocol resubmitted package	AAERC Secretariat
	↓	
2.	Review the revised protocol	AAERC Secretariat/ members/ Chairperson
	↓	
3.	Document the AAERC decision	AAERC Secretariat
	↓	
4.	Communicate the decision	

5. Detailed instructions

5.1 Receive protocol resubmitted package

- Check the distributed packages for
  - Memorandum addressing the corrections,
  - Initial Review Application Form (AA 01-010, see ANNEX 1 of SOP# AA 010)

- Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets, etc are included as part of the package.
- Changes made to the documents should be underlined or highlighted.

❖ Sign and date an acknowledgement form upon receiving the packages.

5.2 Review the revised protocol.

❖ Refer to the meeting minutes as guidance for the review.

❖ Consider whether the recommendation of the AAERC has been followed.

❖ Make further comments where appropriate.

❖ Sign and date the reviewer's name.

❖ Notify the AAERC Secretariat.

5.3 AAERC meeting

❖ The Secretariat receives the review report and informs the Chairperson.

❖ If no AAERC meeting is necessary, then go to step 5.4.

❖ If the AAERC previously decided to see the new revision, then proceed with the following steps:

❖ The primary reviewer presents a brief oral or written summary of the study

❖ Design and his/her comments to the AAERC members.

❖ The Chairperson entertains discussion on the protocol revision.

❖ Further recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes as 'with modifications made by AAERC and will be communicated to the investigator.

❖ The Chairperson calls for a vote on the revision to either:

- Approve the study to start as presented with no modifications = *Approved*
- Approve the study to start with Committee approved modifications to the consent = *Approved with minor modification*
- Require modifications to items noted at the convened meeting and follow-up by the Chairperson, after receipt of the requested modifications = *Approved with major modification*

- *Disapproved*

5.4 Document the AAERC decision.

- Place the original completed documents along with the completed re-review report, the Assessment Form and the Initial Review Application Form as well as the others in the protocol package.
- Prepare an approval letter.
- Send an approval letter to the principal investigator.
- Get the Chairperson's signature.

5.5 Communicate the decision.

5.5.1 Written Communication of the Decision

- The Secretariat notifies the principal investigator about the decision of the AAERC through an e- mail, memo or telephone and files the "sent" and "received" e-mail messages in the protocol file.
- The Secretariat then prepares the Approval/Action Letter and gets the Chairperson's signature.
- If the study is approved, the Committee determines the frequency of Continuing Review for each study site.
  - The Secretariat sends an Action Letter to the investigator notifying the AAERC decision and schedule of continuing review.
  - The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
  - A computer-generated approval and expiration date is placed on every page of each consent form approved by the AAERC.
- If the Committee requires modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator to make the necessary changes and resubmit the documents to the AAERC.

6. Glossary

Document	All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or videotape.
Completed comments Assessment Form	An official record of the review decision along with and dated signature of the reviewer

7. ANNEX

ANNEX 1 AF 01-013 Review of Resubmitted Protocol

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000www.who.int/tdr/publications/publications/.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs: SOP# AA 010.

ANNEX 1 Review of Resubmitted Protocol

Form AF 01-013

Review of Resubmitted Protocol

Protocol No.:		Application No.: □□□ / □□ - □□
Protocol Title:		
Total Participants:		□ 2nd Review □ 3rd Review □ 4th Review
Principal Investigator:		Tel.:
Initial Review Date:		Last Review Date:
AAERC Decision recorded in the meeting minute:	□ Approved with minor changes or recommendation □ Major changes or recommendation need to be reconsidered	
Opinion of the reviewer: □ Revision or Modification according to the recommendation □ What need to be further revised:	□ Yes □ No: Explain:_____	

SIGNATURES:

_____Date:_____ Protocol Reviewer

COMPLETION:

_____ _____

Secretary, AAERC Date

APPROVAL:

_____ _____

Chairperson, AAERC Date

Table Of Contents

1. Purpose

This procedure describes how the Ethics Committee manages continuing reviews of previously approved protocols.

The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants. Continuing review of the study may not be conducted through an expedited review procedure, unless 1) the study was eligible for, and initially reviewed by, an expedited review procedure; or 2) the study has changed such that the only activities remaining are eligible for expedited review.

2. Scope

This SOP applies to conducting any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, they may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the AAERC Secretariat to remind the AAERC and the principal investigators regarding study protocols that should be continuously reviewed. The Chairperson, in consultation with AAERC, is responsible for determining the date of continuing review.

The AAERC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol informed consent documents and assent documents are examined to ensure that the information remains accurate.

The AAERC has the same options for decision making on a continuing review package as for an initial review package. The decision is made as approval; *approval with recommendations; approval with stipulations, pending, or disapproval.*

4. Flow chart

No.	Activity	Responsibility
1.	Determine the date of continuing review	AAERC Secretariat and Chairperson
2.	Notify the study	AAERC Secretariat
3.	Manage continuing review package upon receipt	AAERC Secretariat
4.	Notify the members of the AAERC	AAERC Secretariat
5.	Prepare meeting agenda	AAERC Secretariat and Chairperson
6.	Protocol review process	AAERC Secretariat, Members and Chairperson
7.	Store original documents	AAERC Secretariat Distribute documents to the study team
8.	Distribute documents to the study team	AAERC Secretariat

5. Detailed instructions

5.1. Determine the date of continuing review

- ❖ Look through the document archives for the due date of continuing reviews.
- ❖ Plan for continuing review meeting at least two months ahead and as close as possible to the due date or the anniversary of the effective date. (Date of original approval) of the protocol.
- ❖ Consult the Chairperson for scheduling the Board meeting date.

5.2. Notify the principal investigator or the study team

- ❖ Inform the Study Team at least two months in advance of the due date for the continuing review by fax, post, e-mail or other appropriate means.
- ❖ Fax, mail or e-mail also a Continuing Review Application Form (AA 01-014, see ANNEX 1) to the Study Team to fill up.
- ❖ Keep the informed notice in the correspondence file.
- ❖ Allow the Study Team sufficient time to collate the information and to prepare a report package required for the continuing review.

5.3. Manage continuing review package upon receipt.

- ❖ Receive a package of continuing review for each protocol prepared and submitted by the Study Team.
- ❖ Upon receipt of the package, the Secretariat of the AAERC should perform the

following:

5.3.1. Initial and date the submission package

- ❖ See SOP# AA 007 for procedures on receipt of submitted packages.

5.3.2. Verify the contents of the package.

- ❖ Make sure that the contents of the package include:

  Continuing Review Application Form

  - Check for complete information and for the presence of the required signatures (Protocol Chairperson, if applicable, AAERC Medical Advisor and Medical and Scientific Director of the AHRI/ALERT.
  - See ANNEX 1 for the Continuing Review Application Form (AA 01-013).

  Continuing Review Memorandum with progress report

  - Summarize the progress of the protocol since the time of the last review.
  - Include information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants.

  Current Informed Consent Document

  - Both printed and electronic copies in the Local Area Network (where applicable) in the following drive:
  - C:\AAERCdoc\informconsent\continuereview\file name

- ❖ Verify electronic Informed Consent Document (where applicable).
- ❖ Check if the electronic copy for matches the hard copy submitted by the study team.
- ❖ Store the hard copy with the submitted documents.
- ❖ Clearly identify the document as the hard copy of the electronic informed consent document.
- ❖ Ensure that the version of the informed consent document is the most recently approved informed consent document.

5.3.3. Photocopy the package.

- ❖ Make sufficient copies (for both members and reviewers) of the original continuing review package in accordance with AAERC AA 026 – Procedures

for Maintaining Confidentiality of AAERC Documents.

5.3.4.Store the continuing review package.

- ❖ Store the original package in the protocol specific file.

5.4. Notify the Members of the AAERC

- ❖ Distribute the protocol progress report and the informed consent document to the AAERC.

5.5. Prepare meeting agenda

- ❖ See SOP# AA 021 for procedures on the preparation of meeting agenda.
- ❖ Place the review on the agenda for the meeting of the AAERC which coincides with the anniversary of the protocol effective date (original approval date).
- ❖ Distribute the materials to the AAERC members by electronic mail (e-mail), fax or by post, according to SOP# AA 026 (Procedures for Maintaining Confidentiality of AAERC Documents) at least one and a half to two weeks in advance of the scheduled meeting.
- ❖ Keep copies of "sent" e-mail, fax cover memos and/or letter accompanying posted materials in the Correspondence Section of the protocol specific file.
- ❖ Record and keep the AAERC members' response upon receipt of the agenda in the member correspondence file.

5.6. Protocol Review Process

5.6.1. Continuing Review Application Form

- ❖ Use the Continuing Review Application Form (AA 01-014, see ANNEX 1) to guide the review and deliberation process.
- ❖ Sign and date the Continuing Review Application Form by the
- ❖ Chairperson of the AAERC after a decision has been reached.
- ❖ The completed Continuing Review Applications Form is the official record of the decision reached by the AAERC for the protocol.
- ❖ Maintain and keep the form and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

5.6.2. Final Documentation and Communication of the Decision

- ❖ Complete the printed version of the Continuing Review Application/ Assessment Form by the Chairperson of the AAERC:

- Sign and date the printed version of the form containing the decision and return this to the Secretariat.
- Complete the process within 7 working days of the AAERC meeting.

❖ Complete the original version of the Continuing Review Application Form by the Chairperson:

- Sign and date the original version of the form.
- The Secretariat must sign and date the form.

5.7. Store original documents.

❖ Place the original completed documents with the other documents in the Continuing Review Package in the protocol file.

5.8. Distribute documents to the Study Team.

❖ Distribute copy version of the completed Continuing Review Application/ Assessment Form to the Principal Investigator within 7 working days.

6. Glossary

Approved Protocols Protocols that have been *approved without stipulations* or *approved with recommendations* by the AAERC may proceed.
Protocols that have been *approved with stipulations* by the AAERC may not proceed until the conditions set by the AAERC in the decision have been met. Protocols should be amended and submitted to the AAERC within *one* month for re-review.

7. ANNEX

ANNEX 1 AF 01-014: Continuing Review Application Form (2 pages)

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000 www.who.int/tdr/publications/publications/
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs # AA 007, 026, and 021.

ANNEX 1 Continuing Review Application Form

Form AF 01-014
Page 1 of 2

Continuing Review Application Form

PROTOCOL No.:	ASSIGNED No.: □□□ / □□-□□
PROTOCOL TITLE:	
INSTITUTE MEDICAL ADVISOR:	

ACTION REQUESTED:
Renew - New participant accrual to continue
Renew - Enrolled participant follow up only
Terminate - Protocol discontinued

Have There Been Any Amendments Since The Last Review?
No
Yes (Describe Briefly In Attached Narrative)

SUMMARY OF PROTOCOL PARTICIPANTS:
_____Accrual ceiling set by AAERC
_____New participants accrued since last review
_____Total participants accrued since protocol began

ACCRUAL EXCLUSIONS
NONE
MALE
FEMALE
OTHER (specify: _____)
IMPAIRED PARTICIPANTS
None
Physical
Cognitively Both
HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
NO
YES (Explain changes in attached narrative)
HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?

NO
YES (Explain changes in attached narrative)

Has Any Information Appeared In The Literature, Or Evolved From This Or Similar Research That Might Affect The Iec/Irb's Evaluation Of The Risk/Benefit Analysis Of Human Subjects Involved In This Protocol?

No
Yes (Discuss In The Attached Narrative)
Have Any Unexpected Complications Or Side Effects Been Noted Since Last Review?
No
Yes (Discuss In The Attached Narrative)
HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IEC/IRB APPROVAL?
NO
YES (Discuss in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE
☐ NONE ☐ IND ☐ IDE
DACA No. …….. Name:
…… Sponsor: ……
Holder: ……
IONIZING RADIATION USE (X-rays, radioisotopes, etc)
None
Medically indicated only
HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?
NO
YES (Identify all changes in the attached narrative)
HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
NO
YES (Identify all changes and provide an explanation of changes in the attached narrative)

ANNEX 1
Form AF 01-014

CHANGE IN MEDICAL ADVISOR / INVESTIGATOR? ❑ NONE ❑ DELETE:…… ❑ ADD: ……	HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST? ❑ NO ❑ YES (Append a statement of disclosure)

Preliminary findings _____

Reviewer comments and recommendations _____

SIGNATURES:

_____Date: ……
Protocol Chairperson (if applicable)

_____Date: ……
AHRI/ALERT Medical Advisor

_____Date: ……
AHRI/ALERT Director

AAERC Comment/ Decision:

COMPLETION

_____Date:……
Secretary, AAERC Committee

APPROVALS

_____Date:……
Chairperson, AAERC Committee

Table Of Contents

1. Purpose

The purpose of this SOP is to provide instructions on the review and follow-up, if appropriate, of Final Reports for any study previously approved by the AAERC.

2. Scope

This SOP applies to the review and follow-up of the Final Report which is an obligatory review of each investigator's activities presented as a written report of studies completed to the AAERC.

Although the AAERC provides a Study Report Form (AA 01-015, see ANNEX 1) to the investigator, any mechanism (letter format, form provided by the Sponsor, etc.) may be used, provided that the information submitted is sufficient.

3. Responsibility

It is the responsibility of the AAERC secretariat to review the report for completeness before making copies for the committee meeting.

4. Flow chart

No.	Activity	Responsibility
1.	Receive and check report package	AAERC Secretariat
	↓	
2.	Brief chairperson	AAERC Secretariat
	↓	
3.	Review submitted protocol	AAERC Members
	↓	
4.	Communicate decision	AAERC Secretariat
	↓	
5.	Archive the study protocol and report	AAERC Secretariat

5. Detailed instructions

5.1. Before each Committee meeting

- See SOP# AA 007 (Management of Protocol Submission) for receiving and checking the report packages.
- The Secretariat reviews the submitted report and briefs to the Chairperson.
- Make a sufficient number of copies.

5.2. During the Committee meeting

- Two primary reviewers will take the main responsibility in reviewing protocols for their scientific and ethical validity. The other members will also contribute for the committee's deliberation based on their assessment of the protocol.
- The Chairman or designee entertains any discussion of the study.
- If appropriate to the discussions, an AAERC member may call for consensus on whether to request further information or to take other action with the investigator.
- Summarize what action should be taken: accept as submitted, accept with revision or not approve. This includes the decision made, the period of follow up report expected (3 Months, 6 Months, 9 Months or one year), whether the protocol needs a further review by NRERC and needs of site visit by AAERC?

5.3. After the Committee meeting

- Notify the investigator of the decision.
- Accept and file the Final Report, if no action is taken.
- Note the decision in the meeting minutes
- Consider the study as closed.
- Get a copy of the final report signed by the Chairperson or the designee.
- Send an acknowledged letter to the investigator.
- Archive the entire study protocol and the report.

6. Glossary

7. ANNEX

ANNEX 1 AF 01-015 Study Report Form

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOP#: AA 007.

ANNEX 1 Study Report Form

Form AF 01-015

Study Report Form

Protocol No.:	**Assigned No.:** ☐☐☐ / ☐☐-☐☐	
Protocol Title:		
Principal Investigator:		
Phone number:	**E-mail address:**	
Sponsor's Name		
Address:		
Phone:	**E-mail:**	
Study site(s):		
Total Number of study participants:	**No. of Study Arms:**	
Number of participants who received the test articles:		
Study materials:		
Treatment form:		
Study dose(s):		
Duration of the study		
Objectives:		
Results: (Use extra blank paper, if more space is required.)		
Signature of PI:	Date:	

Table Of Contents

1. Purpose

To provide instructions for taking action and maintaining records that identify investigators/institutes who fail to follow the procedures written in the approved protocol or to comply with national / international guidelines for the conduct of human research, including those who fail to respond to the AAERC requests.

2. Scope

This SOP applies to all AAERC approved research protocols involving human subjects.

3. Responsibility

The Secretariat is responsible for collecting and recording the non-compliance list (AA 01-021).

4. Flow chart

No.	Activity	Responsibility
1.	Noting protocol deviation / non- compliance / violation.	AAERC members and Chairperson
	↓	
2.	AAERC discussion and decision	AAERC members and Chairperson
	↓	
3.	Notify the investigator	AAERC Secretariat
	↓	
4.	Keep records and follow up	AAERC Secretariat

5. Detailed instructions

5.1. Whenever protocol deviation / non-compliance / violation has been observed:

- Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the subsequent AAERC meeting.
- Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the AAERC request for information/action.
- Note: The Board may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

5.2. The AAERC Decision

- The chairperson notifies the investigator of the AAERC action in writing, when the Committee decides to
  - to take no action for minor deviations such as version number change, or
- To do a site visit in projects with major deviations, non-compliance that do pose imminent safety to the study participant, or
- To suspend projects with major non-compliance that pose imminent safety issues of the study participants, or
- to terminate approval of a current study with violation, or
- refuses subsequent applications from an investigator cited for non- compliance.

5.3. Notify the investigator

- The AAERC Secretariat members record the AAERC decision.
- Draft and type a notification letter.
- Get the Chairperson to sign and date the letter.
- Make four copies of the notification letter.
- Send the original copy of the notification to the investigator within the next 7 days.
- Send a copy of the notification to the relevant national authorities and institutes.
- Send the third copy to the sponsor or the sponsor's representative of the study.

5.4. Keep records and follow up

- Keep the last copy of the notification letter in the "non-compliance" file.
- Store the file in the shelf with an appropriate label.
- Follow up the action after a reasonable time.

6. Glossary

Deviation	Departure from the approved protocol, ICH GCP guidelines, Ethiopian National Health Research Ethics Review guidelines/ regulations, and/or the AAERC recommendations.

Non-compliance Failure or refusal to comply with the approved protocol, ICH GCP guidelines, National Ethiopian Health Research Ethics Review guideline regulations, and/or the AAERC requests.

Violation A breach, infringement, or transgression of the guidelines and/or instructions in the approved protocol, ICH GCP guidelines, Ethiopian National Health Research Ethics Review guidelines/ regulations, and/or the AAERC recommendations.

7. ANNEX

ANNEX 1 AF 01-016 Deviation/Non-Compliance/Violation Record

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. National Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014

ANNEX 1 Deviation / Non-Compliance / Violation Record
Form AF 01-016

Deviation / Non-Compliance / Violation Record

Application Number: □□□ / □□ - □□	Date:_____
Study Title:	
Investigator	Contact No.:
Institution:	Contact No.:
Sponsor:	Contact No.:
□ Deviation from protocol □ Non-Compliance □ Major □ Minor □ Violation	
Description:	
AAERC Decision:	
Actions taken:	Outcome:
Found by:_____ Date:_____	Reported by:_____ Date:_____

Table Of Contents

1. Purpose

Since the AAERC considers protection of the rights and welfare of the human subjects participating in clinical investigation/research approved by the AAERC as its primary responsibility, Informed Consent documents reviewed by the AAERC may routinely contain the statement, "Questions regarding the rights of a participant/patient may be addressed to the AAERC Chairperson with the AAERC *address and/or phone number*. On some occasions the first contact a participant/patient may have would be the AAERC Secretariat.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant in any approved research study.

2. Scope

This SOP applies to all requests concerning the rights safety and well-being of the research participants participating in studies approved by the AAERC.

3. Responsibility

The Institute's policy designates the Chairperson of the AAERC as the person responsible for communicating with participants/patients regarding their rights as study participants. Delegation of this responsibility to another AAERC member is acceptable as long as the delegation is documented (in writing). Delegation to non-AAERC members is not permitted.

It is the responsibility of all Staff and AAERC members acting on behalf of the AAERC to facilitate participant/patient requests within the scope of their responsibilities.

4. Flow chart

No.	Activity	Responsibility
1.	Receive the request	AAERC Members and Secretariat
	↓	
2.	Take action	AAERC members and Chairperson
	↓	
3.	Communicate with PI	AAERC Secretariat
	↓	
4.	File the request document	AAERC Secretariat

5. Detailed instructions

5.1 Receive the request.

- The AAERC staff or member receives the inquiry or requests from research participants/patients.
- Record the request and information in the request record form (Form AF 01- 017 see ANNEX 1)
- Communicate with the AAERC about study participant rights for instruction.
- Refer the inquiry to the AAERC Chairperson in writing.
- AHRI/ALERT staff may provide assistance in contacting the Chairperson, but will not provide comments/opinions about the inquiry.
- The Chairperson shall
  - document the communication for the AAERC study file,
  - request follow-up information,
  - provide advice as required,
  - inform the other AAERC members about the inquiry,
  - follow-up at the next AAERC meeting or
  - Delegate these tasks to AAERC Secretariat or members.

5.2 Take Action

- Investigate the fact.
- Record information and any action or follow-up taken in the form AF 01-017.
- Sign and date the form.
- Report to the AAERC about the action taken and the outcomes.

5.3 File the request document

- Keep the record form in the "response" file.
- Keep a copy in the study file.
- Store the file in the appropriately labeled shelf.

6. Glossary

Participants' rights	Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world. … It is essential … that Human Rights should be

protected by the rule of law.

7. ANNEX

ANNEX 1 AF 01-017 Request Record Form

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. www.who.int/tdr/publications/publications/
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. National Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014

ANNEX 1 eRequest Record Form

Form AF 01-017

eRequest Record Form

Date Received:	
Received by:	
Request from:	❑ Telephone call No_____ ❑ Fax No_____ ❑ Mailed letter / Date_____ ❑ E-mail / Date_____ ❑ Walk-in / Date / Time_____ ❑ Other, specify_____
Participant's Name:	
Contact Address: Phone:	
Title of the Participating Study	
Starting date of participation:	
What is requested?	
Action taken:	
Outcome:	

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1. Purpose

This procedure describes how an AAERC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the AAERC, Data Safety Monitoring Board (DSMB), Scientific Director, sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study approved by the AAERC that is being recommended for termination before its scheduled completion.

3. Responsibility

It is the responsibility of the AAERC Chairperson upon the recommendation of the committee to terminate any study that the AAERC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process.

4. Flow chart

No.	Activity	Responsibility
1.	Receive recommendation for study termination	Investigator and AAERC Secretariat
2.	Review and Discuss the Termination Package	AAERC Secretariat and Chairperson
3.	Notify the Principal Investigator	AAERC Secretariat
4.	Store the Protocol Documents	AAERC Secretariat
5.	Inactivate the Protocol Document	AAERC Secretariat

5. Detailed instructions

5.1. Receive recommendation for study termination.

- Receive recommendation and comments from DSMB, AAERC members, Scientific Director, Sponsor or other authorized bodies for study protocol termination.
- Inform the principal investigator or the study office to prepare and submit a protocol termination package.
- Receive the study protocol termination package prepared and submitted by the

principal investigator or the study office.

- Verify the contents of the package for inclusion of:
  - Request for Termination Memorandum (AA 01-018, see ANNEX 1 of this SOP.)
  - The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.
  - Original Continuing Review Application Form (AA 01-014), see ANNEX 1 of SOP# AA 014.
  - Termination is indicated under "Action Request".
  - Completeness of the information, including accrual data since the time of the last continuing review.
  - Presence of the required signatures (Principal Investigator).
- Initial and date the package upon receipt.

5.2. Review and discuss the Termination Package.

- Notify the Chairperson regarding the recommendation for study protocol termination.
- Send a copy of the termination package to the Chairperson within five working days upon receipt.
- The Chairperson reviews the results, reasons and accrual data.
- The Chairperson calls for an emergency meeting of the AAERC to discuss about the recommendation.
- The committee approves/or recommends changes to the termination package
- The Chairperson signs and dates the Continuing Review Application
- Form in acknowledgment and approval of the termination.
- The Chairperson returns the form back to the Secretariat within 5 working days of receipt of the package.
- The Secretariat reviews, signs, and dates the Continuing Review
- Application Form indicating that the termination process is complete.

5.3. Notify the Principal Investigator.

- Make a copy of the completed Continuing Review Application Form
- Send the copy to the principal investigator for their records within 7 working days.

5.4. Store the protocol documents.

- ❖ Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file.
- ❖ Send the file to archive.
- ❖ Store the protocol documents indefinitely.

5.5. Inactivate the protocol documents.

- ❖ Place the study protocol into the inactive protocol folder in the computer records under the following directory: F:\studyfiles\inactive protocols

6. Glossary

7. ANNEX

ANNEX 1 AF 01-018 Study Termination Memorandum

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOP: SOP# AA 014, AA 018.
4. National Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014

ANNEX 1 Study Termination Memorandum

Form AF 01-018

Study Termination Memorandum

PROTOCOL NUMBER:	ASSIGNED No.: □□□ / □□-□□		
PROTOCOL TITLE:			
PRINCIPAL INVESTIGATOR:			
PHONE :	E-MAIL:		
INSTITUTE:			
SPONSOR:			
AAERC APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS:		NO. ENROLLED:	
SUMMARY OF RESULTS			
ACCRUAL DATA:			
P.I. SIGNATURE:		DATE:	

Table Of Contents

1. Purpose

The purpose of this SOP is to provide instructions on the review and follow-up reports of serious adverse experience and unexpected events for any active study approved by the AAERC. The investigators or sponsors must report the SAE within 10 working days after the incident occurred and unexpected events should be included in the continuing review report submitted to AAERC.

Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the AAERC to ensure adequate protection of the welfare of the study participants.

The unanticipated risks may as well include any event that in the investigator's opinion may adversely affect the rights, welfare or safety of subjects in the study.

2. Scope

This SOP applies to the review of SAE and unexpected events reports submitted by investigators, Data Safety Monitoring Board (DSMB), sponsor, local safety monitor, AAERC members or other concerned parties.

3. Responsibility

The primary responsibility of the AAERC is to review and address SAE and unexpected events involving risks to subjects or others as well as ethics complaints. In addition, the Committee is authorized to offer mediation under appropriate circumstances.

AAERC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

The AAERC Secretariat is responsible for first screening the assessment of the reports and seeing whether they need a review of full Board, Chairperson, other qualified AAERC members or experts.

4. Flow chart

No.	Activity	Responsibility
1.	SAE related activities before an AAERC meeting	
1.1.	Review and determine the review channel	AAERC Secretariat Members
1.2.	Criteria for the review	AAERC Secretariat / SAE focal person
2.	During the AAERC meeting	AAERC members and Chairperson
2.1.	Review and discuss	AAERC members and Chairperson
2.2.	Decide what action should be taken	
2.3.	Inform investigator or clinical trial office	AAERC Secretariat and Chairperson

5. Detailed instructions

5.1. Before each AAERC meeting

5.1.1. Review and determine the review channel

- The chairperson / SAE focal person designated by the chairperson reviews the SAE and recommends to the secretariat the actions to be taken, including determination of whether or not the report requires review by full Board.

5.1.2. Criteria for the review

- The review criteria are as follows:
  - Report is forwarded to the SAE focal person for review and determine if the report is expected or not expected, related or not related.
  - The SAE focal person and Chair will determine if the report should be reviewed at the convened meeting by full Board.
  - Assessment of Serious Adverse event is possibly unexpected and related to the investigational product.
  - The report is added to the agenda for review at a convened meeting by full Board.
  - SAE /IND Safety Report has been previously seen by full Board but being resubmitted by another investigator participating in the multi-study site (as part of a multi-center/site study), or is offsite. This notification does not require full

Board review. Reviewed by the Chairperson and SAE focal person and communicated to the PI

- The report is added to the agenda for review at a convened meeting by full Board.
- An adverse experience/IND Safety Report has been previously seen by full Board but being resubmitted by another investigator participating in the multi-study site (as part of a multi-center/site study).
- This notification does not require full Board review.
- Reviewed by the Chairperson or other qualified AAERC members and secretariat

5.2. During the AAERC meeting

5.2.1. Review and discuss

- After reading and reviewing the report, the Chairperson or designee entertains discussion on the study and similar adverse experiences or advisories.
- If appropriate to the discussions, the Chairperson or another Board member may call for a consensus on whether to:
  - *Request an amendment to the protocol or the consent form.*
  - *Request further information.*
  - *Suspend or terminate the study.*

5.2.2. Decide what action should be taken.

- If any of the above actions are taken, the AAERC Secretariat or designee notifies the investigator of the action taken.
- If the AAERC takes no action, a notation is made in the minutes and the study is allowed to continue.

5.2.3. Inform investigator or clinical trial office

- The AAERC secretariat member drafts a formal letter to the investigators or the clinical trial office to notify them of the action they should take according to the AAERC decision.
- Get the Chairperson to approve, sign and date the letter.
- Send the letter and record the delivery date.

6. Glossary

Adverse Event — Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

Adverse Drug Reaction — In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

IND — Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.

SAE (Serious Adverse Event) — The adverse event is SERIOUS and should be reported when the patient outcome is:

Death - Report if the patient's death is suspected as being a direct outcome of the adverse event.

Life Threatening - Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.

Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.

Hospitalization (initial or prolonged) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event.

Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.

Disability - Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life.

Examples: Cerebrovascular accident due to drug- induced hypercoagulability;toxicity; peripheral neuropathy.

Congenital Anomaly - Report if there are suspicions of exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.

Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.

Requires Intervention to Prevent Permanent Impairment or Damage – Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.

Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.

Unexpected ADR Unexpected Adverse Drug Reaction is an adverse reaction, the nature or severity of which is not consistent with the informed consent / information sheets or the applicable product

information (e.g., investigator's brochure for the unapproved investigational product or package insert / summary of product characteristics for an approved product.

7. ANNEX

ANNEX 1	AF 01-019	Serious Adverse Event Report
ANNEX 2	AF 02-019	Unexpected Adverse Drug Reaction Report

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1 SeSerious Adverse Event Report

ANNEX 1
AF 01-019

Principal Investigator:…….. Application No: ☐☐☐/☐☐-☐☐

Study Title:…… Protocol No.:

Name of the study medicine/device……..…… Report Date: ……
☐ initial ☐ follow-up
Onset date:……

Sponsor:…… Date of first use: ……..

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐ resolved ☐ on-going	
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization –○ initial ○ prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other……	Relation to ○ Drug ○ Device ○ study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown	
Changes to the protocol recommended?	☐ No ☐ Yes , attach proposal	
Changes to the informed consent form recommended?	☐ No ☐ Yes , attach proposal	
Reviewed by:…… Comment:…… ……	Date:…… Action:…… ……	

ANNEX 2 Unexpected Drug Adverse Event Report

ANNEX 2
AF 02-019

Unexpected Drug Adverse Event Report

Application No: ☐☐☐ / ☐☐ - ☐☐

Principal Investigator……..

Study Title……. Protocol No.:

Name of the study medicine/device……

Report Date: ……
☐ initial ☐ follow-up
Onset date……

Sponsor……

Date of first use:
……..

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:		Laboratory findings:
Unexpected Drug AE: (describe event chronologically) _____ _____ _____ _____ _____		Management: Outcome: ☐ resolved ☐ on-going
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization –○ initial □ prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other……		Relation to ○ Drug ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown
Changes to the protocol recommended?		☐ No ☐ Yes, attach proposal
Changes to the informed consent form recommended?		☐ No ☐ Yes, attach proposal
Reviewed by…… Comment……		Date…… Action…… ……

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1. Purpose

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored for its performance or compliance to GCP.

2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the AAERC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed. Ideally, especially in the case of field studies, the AAERC may wish to conduct report back visits involving the study site personnel and relevant (Regional) Health Bureau and Medical/ University staff.

3. Responsibility

It is the responsibility of the AAERC to perform or designate some qualified agents to perform on its behalf on-site inspection of the research projects it has approved.

The AAERC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

4. Flow chart

No.	Activity	Responsibility
1.	Selection of study sites	AAERC members and Chairperson
	↓	
2.	Selection of site monitors	AAERC members and Chairperson
	↓	
3.	Preparation before the visit	AAERC members and/or representative
	↓	
4.	Procedures during the visit	AAERC members and/or representative
	↓	
5.	Procedures after the visit	AAERC members and/or representative
	↓	
6.	Present the findings to the Full Board	AAERC members and/or representative

5. Detailed instructions

5.1.Selection of study sites

- Review periodically the database files of the submitted/approved study protocols.
- Select study sites needed to be monitored based on the following criteria:
- When the AAERC has never approved the principal investigator for a research

project, a study visit should be planned for at the appropriate time after the study starts.

- New study sites
- Reports of remarkable serious adverse events
- Number of studies carried out at the study sites.
- Frequency of protocol submission for the AAERC review
- Non-compliance or suspicious conduct
- Frequently fail to submit final reports
- Studies which are high risk
- Studies where the PI has several on-going studies (more than three)

5.2. Selection of Monitors

- Monitors will be selected from the members of the AAERC according to their professional expertise and the expertise required for the study.

5.3. Before the visit

The AAERC representatives will

- Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate a time for the site evaluation visit.
- Make the appropriate travel arrangements.
- Review the AAERC files for the study and site,
- Make appropriate notes, or
- Copy some parts of the files for comparison with the site files.

5.4. During the visit

- Get a checklist AA 01-020 (ANNEX 1).
- The AAERC representatives will
  - Review the informed consent document to make sure that the site is using the most recent version,
  - Review randomly the subject files to ensure that subjects are signing the correct informed consent,
  - Observe the informed consent process, if possible,
  - Observe laboratory and other facilities necessary for the study at the site.

- Observe security of files and how confidentiality maintained
- Review the AAERC files for the study to ensure that documentation is filed appropriately.
- Observe security of files and how confidentiality is maintained.
- Collect views of the study participants.
- Debrief the visit report/comments.
- Get immediate feedback.

5.5. After the visit

The AAERC representative will:

- Write a report/comment (use the form AA 01-020, see ANNEX 1) within 2 weeks describing the findings during the audit
- Forward a copy of the site visit to the 'site monitoring' file for Full Board review.
- Send a copy of the report to the site for their files, and
- Place the report in the correct site files.

5.6. Present the inspection results to the Full Board

- Consult with the AAERC secretariat.
- Schedule the presentation in the meeting agenda.
- Present the results of on-site inspections to the Full Committee.

6. Glossary

AAERC representatives	Many AAERC members rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to AAERC.
Monitoring visit	An action that AAERC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

7. ANNEX

ANNEX 1AF 01-020: Checklist of a Monitoring Visit

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000 www.who.int/tdr/publications/publications/.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. National Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014

ANNEX 1 Checklist of a Monitoring Visit
AF 01-020

Checklist of a Monitoring Visit

Application No.: ☐☐☐ / ☐☐ - ☐☐		Date of the Visit:
Study Title:		
Principal Investigators:		Phone:
Institute:		Address:
Sponsor:		Address:
Total number of expected subjects:		Total subjects enrolled:
Are site facilities appropriate? ☐ Yes ☐ No		Comment:
Are Informed Consent forms the recent approved version ? ☐ Yes ☐ No		Comment:
Any adverse events found? ☐ Yes ☐ No		Comment:
Any protocol non-compliance /violation? ☐ Yes ☐ No		Comment:
Are all Case Record Forms up to date? ☐ Yes ☐ No		Comment:
Are storage of data and investigating products locked? ☐ Yes ☐ No		Comment:
How well are participants protected? ☐ Good ☐ Fair ☐ Not good		Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No		Give details:
Results of Interview with Study Participant? ☐ Yes ☐ No		Give details:
Duration of visit: ……hours	Starting from:	Finish:
Name of AAERC member/ representatives and accompanies:		
Completed by:		Date:

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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 the AAERC meetings.

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda for all regular AAERC meetings, divided into three stages: before, during and after the meeting.

3. Responsibility

It is the responsibility of the Secretariat staff to prepare the agenda for the AAERC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the agenda and the minutes sent to him/her. Previous minutes shall be prepared and presented to the committee for approval.

4. Flow chart

No.	Activity	Responsibility
1.	Before each Committee Meeting	Administrative staff / AAERC Secretariat
	↓	
2.	During the Meeting	AAERC Secretariat, Members and Chairperson
	↓	
3.	Voting	AAERC Members without conflict of interest / Chairperson
	↓	
4.	After the Committee Meeting	AAERC Secretariat / Chairperson
	↓	
5.	Preparing the Meeting Minutes	AAERC Secretariat staff / Chairperson

5. Detailed instructions

5.1. Before each AAERC meeting

5.1.1. Check for filled up forms for completeness.

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

5.1.2. Prepare meeting agenda

- Schedule the review as soon as possible after submission, either at the time of the next scheduled meeting or within 4 weeks after submission.
  - Arrange extra AAERC meetings to accommodate protocol reviews.
- Consult the Chairperson to schedule the meeting date.
- Prepare the meeting agenda, according to the format shown in ANNEX 1 (AA 01-021).
- 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 to the reviewers and the members.
  - Allow at least 1 weeks for the review process.
- Include a protocol assessment form (AA 01-010) with the protocol package along with the invitation letter, a response form and the meeting agenda.
- In the case of an expedited review, specify the due date for the return of comments.
- For regular review, the reviewers bring their comments and assessment forms for discussion in the next board meeting.
- Write down the running number of the protocol in the square boxes at the bottom right corner of the form AA 01-010.
- Sign the second page of the form AA 01-010.
- Prepare the package for delivery.

- Record the name of the assigned reviewers in the appropriate database or the review assignment file.

5.1.3.Distribution of Protocol Packages to the AAERC Members

- Keep in mind Procedure for Maintaining Confidentiality of the AAERC documents (SOP# AA 026) when preparing and distributing documents.
- Distribute copies of the protocol submission packages to the assigned reviewers and the AAERC members by either electronic mail (if electronic submission protocols), tele-fax by post two weeks in advance of the scheduled meeting, or by a designated institution vehicle and driver.
- Keep copies of "sent" e-mail, fax cover memos and/or letters accompanying posted materials in the Correspondence section of the respective protocol file.
- Verify (verbally, by e-mail, by fax or by mail) with the members whether the protocol packages are received.

5.1.4.Prepare for the meeting

- Make a room reservation on the schedule meeting date and time.
- Make sure that the room, equipment and facilities are available in good running condition and cleaned for the meeting day.
- Make sure that members are reminded at least two days before for the meeting.

5.2. During the meeting

- The Chair determines that quorum is met. Quorum of AAERC is when 50 % +1 of the members are present
- The AAERC 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 (AA 02-004, see ANNEX 2 of SOP# AA 004).
- The Secretariat reports on the minutes of the previous meeting and presents the agenda for discussion.

- Any other business (AOB) raised for discussion is added to the agenda at the beginning of the meeting.
- Before the review process begins, members declare any conflict of interest they have and request to be excused during the review of that protocol.
- 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.
- The members give their comments and the points in the assessment form are discussed by all members. These discussions are documented in the Minutes and the comments to be given to the investigator are derived from the minutes and include only the comments where the members have consensus.
- In case the reviewer cannot be present during the meeting, a member of the Secretariat or an AAERC 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 AAERC members may have.

5.3. Voting/decision

- All decision will take place after the observers / presenters / board members with a conflict of interest leave the meeting room.
- The decision is usually done by consensus but if a consensus cannot be reached, then decision is made by voting. In order to avoid conflict of interest, only those AAERC members who are independent of the investigator and the sponsor of the trial will vote on the research-related matters.
- The Chairperson determines if the number of voting AAERC members is

sufficient to constitute a quorum and proceeds accordingly.

- ❖ AAERC member makes a motion to recommend action on a protocol or issue being discussed.
- ❖ The motion is seconded, and voting takes place.
- ❖ A motion is carried out once the majority of the AAERC members vote in favor of the motion.
- ❖ If there is a tie in voting the chairperson has the casting vote.

5.4. After the AAERC meeting,

- ❖ As soon as possible after each meeting, a copy of the minutes is sent to the secretary for quality control and review.
- ❖ The secretary 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 secretariat 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 (Form AF 02-021) 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 two weeks after the meeting.

5.5.2. Contents of the AAERC Meeting Minutes

- ❖ The official minutes of the AAERC 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
- 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 AAERC'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.

❖ Secure the approval of the AAERC members

❖ Get the Chairperson and the secretary of the AAERC to sign and date the relevant sections of the minutes of the AAERC meeting and the decision form.

5.5.4. Filing the minutes

❖ Place the comments given to the PI and the signed decision form in the AAERC files for the specific protocol

❖ Place all correspondence in the appropriate file.

❖ Place the signed minutes in the "Minutes" Folder.

❖ Place a copy of the approval letter in the "Minutes" folder.

5.5.5. Distributing the minutes and the decision

❖ Send a copy of the relevant sections of the minutes ("Comments given to PI" and the decision form to the applicants for their records by mail or other means.

❖ Send the approved minutes to the AAERC members.

❖ Send the decision of the AAERC 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 the AAERC 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 vote in its favor.

7. ANNEX

ANNEX 1	AA 01-021	Agenda format
ANNEX 2	AF 02-021	Form of AAERC Meeting Minutes

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs # AA 004-006, 007,009-015, 026.

ANNEX 1 Format of an Agenda

AA 01-021

Agenda of the AAERC Meeting

Agenda No.	Meeting No.	Meeting Location	Meeting Date and Time

The Committee meeting will proceed in the following sequence: Period 1 Issues to be informed to the members.

Period 2 Approval of the last meeting minute

Minutes No.	Date

Period 3 Protocol Presentation, Review, Discussion and Voting

1. Protocols submitted for Initial Review

Protocol No.	Title	PI

2. Resubmitted protocols

Protocol No.	Title	PI

3. Protocols requesting for an amendment

Protocol No.	Title	PI

4. Protocols for continuous Review

Protocol No.	Title	PI

5. Site visits

Protocol No.	Title	PI

6. Report of expedited protocols

Period 4 Issues to be reported for Consideration

Period 5 Other issues of interest to the members

Form of AAERC Meeting Minutes

ANNEX 2
AF 02-021

Form of AAERC Meeting Minutes

Meeting No.:	Meeting date:
☐ Regular meeting	☐ Emergency meeting
Location where the meeting is held (city, state)	
Agenda items:	
Starting time:	Adjourned time:

Attending committee members and guests:

Members Present	**Members Excused**	**Members Absent**

Individual serving as Chairman of the meeting:
Determination of a duly constituted quorum by the Chairman to proceed with the meeting

Agenda:

1 Approval of Agenda
2 Declaration of Conflict of Interest
3 Approval of Minutes
4 Matters arising from previous minutes
5 Protocols submitted for initial review
6 Resubmitted protocols for review
7 Protocols submitted for amendment
8 SAE Report
9 Protocol submitted for expedited
10 Protocol submitted for exemption
11 Protocol progress reviewed
12 A.O.B.

Prepared by_____ Reviewed by_____

Date:_____ Date: _____

Approved by_____
Date: _____

Table Of Contents

1. Purpose

The purpose of this SOP is:

- to identify the administrative process for preparing for an emergency meeting.
- to provide instructions on the review and approval of study activities using the Emergency Meeting Procedure

2. Scope

This SOP applies to emergency AAERC meetings.

Emergency meetings may be scheduled to review/approve safety / life threatening issues, new studies, and additional investigators, continuing review, protocol amendments and other study activities that require full Board review.

For routine medical research studies, a physician may be invited to attend the meeting to provide necessary detailed information on medical care given to participants. For certain dental studies, it may be necessary to invite a dentist to attend the meeting as well.

3. Responsibility

- The AAERC Chairperson may call for an emergency meeting as appropriate.
- Any AAERC member may request the chairperson to call emergency meeting

4. Flow chart

No.	Activity	Responsibility
1.	Preparation for the AAERC meeting	AAERC Secretariat
2.	AAERC meeting	AAERC Members and Chairperson
3.	Actions taken after the meeting	AAERC Secretariat
4.	Archiving the communication	AAERC Secretariat

5. Detailed instructions

5.1. Preparation for the AAERC meeting

- Decide to call an emergency meeting based on the following criteria:
  - Urgent issues (if delay will affect or have impact to the public benefit, national economics, etc.)
  - Occurrence of unexpected serious adverse events.
  - A matter of life and death

- Other appropriate reasons.

❖ Contact and inform AAERC members, including the invited persons about the meeting.

- At least one scientific member
- A non-scientific member
- A member with expertise on the item to discussed
- For routine medical research studies, a physician may be invited.
- For certain dental studies, a dentist may be invited.

❖ Invite at least one expert to look at the document, as appropriate.

❖ Prepare packets for distribution to the members.

❖ Attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendant confirmation form to the packets.

❖ Refer to the relevant SOPs (i.e., SOP # AA 010 - Initial Review of Application Protocol, SOP# AA 009 - Expedited Review, SOP# AA 012 Review of Protocol Amendments, etc.)

5.2. During the meeting

❖ Determine if there is a quorum.

❖ Follow the related SOPs

- SOP# AA 003 Constituting an Ethics Committee
- SOP# AA 007 Management of Protocol Submission
- SOP#AA 008 Use of Assessment Form
- SOP# AA 009 Expedited Review
- SOP# AA010 Initial Review of Application Protocol
- SOP# AA 012 Review of Protocol Amendments
- SOP# AA 014 Continuing Review
- SOP#AA 021 Preparation of Meeting, Agenda, Minutes and Action letters
- SOP# AA 011 – Review of New Medical Device Studies

5.3. After the meeting

❖ Follow the related SOPs in 5.2.

❖ The secretariat shall follow the relevant SOPs in 8.2 for preparation and documentation of the minutes.

- ❖ The secretary shall take all the actions deemed necessary during the meeting.
- ❖ This may include, informing the investigator/ PI/ Sponsor/ the decision and recommendations of the AAERC.

6. Glossary

Emergency meeting	An AAERC meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full AAERC review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion and voting portions of the meeting. Emergency meetings may be held via teleconference, if applicable.

7. Annex

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs: AA 003, 007-011, 012-014 and 021.

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1. Purpose

The purpose of this SOP is to ensure proper completion, distribution and filing of verbal and written communication and other study-related or process-related information done with investigators, sponsors, volunteer subjects, institutes and/or relevant government agencies (DACA, etc.).

2. Scope

This SOP applies to all communicating activities related to the studies under the approval of the AAERC.

3. Responsibility

It is the responsibility of all AAERC administrative staff, Board members, secretariat and chairperson conducting activities with the AAERC to complete a written communication record for telephone or interpersonal discussions related to past, present and/or future studies and/or processes involving the AAERC.

4. Flow chart

No.	Activity	Responsibility
1.	Recording of communication	AAERC Secretariat /members/ Chairperson
	↓	
2.	Documentation of the contents of the communication	AAERC Secretariat /members / Chairperson
	↓	
3.	Distribution of the record	AAERC Secretariat /members / Chairperson
	↓	
4.	Archiving the communication	AAERC Secretariat

5. Detailed instruction

5.1. Communication recording mechanism

- Individuals may utilize different communication recording mechanisms that may be handwritten, typed or computer-generated.

5.2. Contents of a written record

- The record should contain, but is not limited to, the following information:
  - Date of communication

- Study information, i.e., sponsor, protocol number, investigator, etc.
- Copy of signed informed consent to be placed with the study participant
- Name of person contacted
- Contact address, telephone number, and e-mail
- Summary of the communication made
- Notation of any follow-up necessary
- Signature of individual completing record
- Name and signature of tracer on a filled-up records

5.3. Distribution of the record

- Upon completion of the records, the individual distributes copies to:
  - The study file
  - Others, as appropriate
  - Secretariat or administrative staff for filing

6. Glossary

7. Annex

Annex 1 AF 01-023 Communication Record Form

8. Reference

ANNEX 1 Communication Record Form

ANNEX 1
AF 01-023
Page 1 of 1

Communication Record Form

		Date:	
Means of Contact	☐ Telephone ☐ Fax ☐ e-mail ☐ In Person		
Status of Contact	☐ Incoming call		
Person contacted:	☐ Reviewer ..... ☐ Chairperson ..... ☐ Sponsor ☐ Investigator ☐ Media ☐ Subject ☐ Institute ☐ Regulatory		
Name:			
Telephone No.		Fax No.	
e-mail			
Protocol No.			
Title :			
Communication Issues / Reason for making contact:			
Follow-up Action :	☐ Return call ☐ will call again ☐ None ☐ See notes ☐ Circulation ☐ Confidential		
Summary of Communication:			
Recorded by:			

Contact address_____
Telephone number_____

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1. Purpose

To provide instructions for preparation, circulation and maintenance of documentation active study files and other related documents approved by the AAERC.

2. Scope

This SOP applies to all active study files and their related documents that are maintained in the AAERC office.

3. Responsibility

It is the responsibility of AAERC Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

4. Flow chart

No.	Activity	Responsibility
1.	Organize the contents of the active study files	AAERC Secretariat
	↓	
2.	Maintain the active study files	AAERC Secretariat

5. Detailed instruction

5.1. Organize the contents of the active study files

- Get the master copy of the study files.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum, the following documents:
  - Original applications and any updates received during the study.
  - Investigator's brochures or similar documents
  - Approval letters and other correspondence sent to the investigator.
  - Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
  - Adverse experience reports or IND safety reports received
  - Continuing review reports
  - Use a folder with the following on the cover:
  - The name of the sponsor

- The protocol numbers
- The number assigned by the AAERC Secretariat

❖ Put the following into each folder with the following information:

- Sponsor with address and contact phone/e-mail id of contact person, protocol number, investigator name (with address, e-mail, telephone and fax) and title
- Application form of the AAERC Protocol, Case Report Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data, any other material submitted by the investigator
  - Correspondence
  - Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
  - Revisions/Amendments
  - Adverse Events
  - Continuing Review, if applicable
  - Final report

5.2. Maintain the active study files

❖ Assign the approved study files with unique identifiers (on a sheet of paper) established by a member of the AAERC Secretariat

❖ Combine related documents of the approved study files appropriately.

❖ Attach an identity Label to the package.

❖ Keep all active and potential study packages in a secure file cabinet.

❖ Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the AAERC.

❖ Send all closed study files to archive.

❖ Store the closed study files for at least 5 years after the study closure.

Note: For studies with multiple study sites, a member Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.

Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.
CRF	Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.
IND	Investigational New Drug is a drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites.
ICD	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Master file	A file for storage of the originally signed and dated documents

6. ANNEX

7. Reference

Table Of Contents

1. Purpose

To provide instructions for storing *inactive* study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors.

2. Scope

This SOP applies to archiving the study files and administrative documents that are retained for at least five years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. Responsibility

It is the responsibility of AAERC Secretariat for maintaining inactive study files and administrative documents.

4. Flow chart

No.	Activity	Responsibility
9.	Prepare documents for archiving	AAERC members, Secretariat
	↓	
10.	Archiving documents	AAERC Secretariat
	↓	
11.	Retrieving Documents	AAERC Secretariat
	↓	

5. Detailed instruction

5.1. After receiving the final report

- AAERC Secretariat and Members review the Final Report of the study.
- A member of the Secretariat should
  - Remove the contents of the entire file from the active study filing area.
  - Verify that all documents are present in an organized manner.
  - Obtain an archive number from the AHRI/ALERT Archives Department.
  - Enter the number into the file and the data base.
  - place the file in a storage container
  - Send to the archives.

- ❖ Hold the files of multi-center studies, until all the study sites are closed.
- ❖ Place in a storage container together.
- ❖ Send to the archive.

5.2. When archiving administrative documents

A staff of the AAERC Secretariat should

- ❖ perform inventories of miscellaneous administrative documents
- ❖ place the documents in the appropriate storage container, and
- ❖ send it to the appropriate storage facility so that it may be easily retrieved.

Note: The AAERC Secretariat maintains past board membership information as well as the active administrative documents.

5.3. Retrieving Documents

- ❖ Keep in mind the SOP/026/01.0 (Maintaining Confidentiality of Ethical Review Committee Documents)
- ❖ Retrieval of documents can only be done with a request form (AF/01-025/01.0, see ANNEX 1) signed and dated by the AAERC Chairperson or the Secretariat.
- ❖ The requestor must also sign and date the log of request (AF/02-025/01.0, see ANNEX 2)
- ❖ The Secretariat retrieves archived documents in compliance with the procedures of the AHRI/ALERT Archives department and refers to the inventory kept by AHRI/ALERT.
- ❖ Return the file back to its place.
- ❖ Record, sign and date when the document has been returned and kept.

6. Glossary

Administrative Documents	Documents include official minutes of Committee meetings (as described in SOP/021/01.0) and the Standard Operating Procedures, both historical files and Master Files as described in SOP/001/01.0.
Inactive Study Files	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and

correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the AAERC for which a final report has been reviewed and accepted.

7. ANNEX

ANNEX 1	AF 01-025	Document Request Form
ANNEX 2	AF 02-025	Log of Requested AAERC

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs: SOP AA 021

ANNEX 1 Document Request Form

ANNEX 1
Form AF 01-025

Document Request Form

Name of Document requested:	Code:
Requested by:	Date:
☐ Chairperson ☐ Secretariat ☐ AAERC Member	
☐ Secretariat staff ☐ Authority ☐ Others……..	
Purpose of the request:	
Retrieved by:	Date:
Approved by:	Date:
Returned by:	Date:
Archived by:	Date:

ANNEX 2 Log of Requested AAERC Documents

ANNEX 2
Form AF02-025

Log of Requested AAERC Documents

#	Document	Requester	Date Requested	Retrieved by	Archived by	Returned Date

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1. Purpose

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle original documents and copies of documents in order to protect confidentiality of documents.

2. Scope

This SOP applies to all kinds of handling, distribution and storage of submitted study protocols, AAERC documents, and correspondence with experts, auditors and the general public.

3. Responsibility

Confidentiality of study protocols, AAERC documents, and correspondence with experts and auditors is mandatory. AAERC members and staff have signed confidentiality agreements with the institute that enforces confidentiality.

If non-members of the AAERC need copies of documents, it is the responsibility of the AAERC member/staff requesting a copy on behalf of the non-members to maintain confidentiality of documents.

4. Flow chart

No.	Activity	Responsibility
1.	Access to AAERC document	AAERC members and Secretariat
	↓	
2.	Classify confidential documents	AAERC members and Secretariat
	↓	
3.	Copy confidential documents	AAERC Secretariat
	↓	
4.	File Log of Copies	AAERC Secretariat

5. Detailed instructions

5.1. Access to AAERC Documents

The AAERC members and the staff of the Secretariat of the AAERC, who must read, understand and agree to the following:

5.1.1 Members of the AAERC

- Sign a confidentiality agreement (AA 01-004) with AHRI/ALERT before the start of any activity for the AAERC.
- Shall have access to all AAERC documents.

5.1.2 Secretariat of the AAERC

- The secretary of the AAERC is a staff member of AHRI/ALERT.
- Sign a confidentiality agreement with AHRI/ALERT
- Have access to any document issued by or to the AAERC, according to SOP# AA 026 (Maintaining Confidentiality of AAERC Documents).

5.2. Classify confidential documents.

- Types of documents

  The types of documents reviewed by AAERC members include:

  - Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
  - AAERC documents (meeting minutes, advice and decisions)
  - Correspondence (experts, auditors, study participants, etc.)

  Note: Copies of all versions of documents, including draft and sequential definitive versions, are to be kept private and confidential with the exception of those made according to the following sections.

5.3. Copy confidential documents

Copies of documents, including draft and sequential versions, are considered to be confidential and are not permitted to be brought out *except when a document is needed for day-to-day operations.*

5.3.1. Copy Authorization

- Only members of the AAERC are allowed to ask for copies.
- Only staff members of the Secretariat of the AAERC are allowed to make such copies.
- The Secretariat of the AAERC may ask for help, but is responsible for maintaining confidentiality of all documents.

5.3.2. Log of Copies

- A Log of Copies (see ANNEX 1 Form AA 01-026) must be kept by the Secretariat.

- ❖ The log should include: the name and signature of the individual receiving the copy; the initial of the AAERC Secretary who made the copy; the number of copies made and the date that the copies were made.

5.3.3. Copies requested by non-members of the AAERC

- ❖ Copies of AAERC documents requested by non-members of the AAERC (including the Secretary) can only be given after the permission from the Chairperson of the AAERC and the person requesting for the document signs a confidentiality agreement form (AA 03-004).
- ❖ Copies made for non-members of the AAERC must be recorded in both the Log of Requests for Copies of AAERC documents (AA01-026) and the log of Copies of the Original Documents (AA 02-026).

5.4. File Log of Copies.

- ❖ The Log of Copies of Original Documents must be stored with the original documents.
- ❖ The Log of Copies of Original Documents is not a confidential document and can be reviewed upon request.
- ❖ A Log of Copies of Original Documents must be maintained.

6. Glossary

Document	Documents mean the followings: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - AAERC documents (SOPs, meeting minutes, advice and decisions) - Correspondence (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Non-members of the AAERC	Any relevant person/persons who presently is/are not a member/members of the AAERC such as authorities, monitors, auditors, subjects, etc.

7. ANNEX

ANNEX 1	AF 01-026	Log of Requests for Copies of AAERC Documents
ANNEX 2	AF 02-026	Log of Copies of Original Documents

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Related SOPs: AA # 004

ANNEX 1 Log of Requests for Copies of AAERC's Documents

ANNEX 1
Form AF 01-026

Log of Requests for Copies of AAERC's Documents

#	Documents requested	# of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

ANNEX 2 Log of Copies of Original Documents

ANNEX 2

Form AF 02-026

Log of Copies of Original Documents

Title of the Document:…….

……..

#	Name of Recipient	# of Copies	Reasons of the Request	Signature of Recipient	Secretariat Initials	Date

Note: *This log should be attached to the original documents.*

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1. Purpose

The purpose of this procedure is to guide how to prepare for an audit or inspection of the AAERC processes.

2. Scope

This SOP applies to every unit of the AAERC Office.

3. Responsibility

It is the responsibility of the Secretariat, the Members, and the Chairperson of the AAERC to perform all tasks according to the SOPs and to be well-prepared and available to answer questions during evaluation, audit or inspection visits of authorities and guests.

4. Flow chart

No.	Activity	Responsibility
1.	Call for an Audit / Inspection	AAERC Chairperson / Director of the Institution
	↓	
2.	Prepare for the visit	AAERC Secretariat / Members and Chairperson
	↓	
3.	Welcome Auditor / Inspector	AAERC Secretariat / Members And Chairperson
	↓	
4.	Correct the mistakes	AAERC Secretariat / Members and Chairperson

5. Detailed instructions

5.1. Call for an Audit / Inspection

- Receive a notice of inspection visit
- The Chairperson informs the Secretariat / Director or Head of AHRI/ALERT.
- The Chairperson alerts every unit to get ready.

5.2. Prepare for the visit

- Get a checklist AA 01-027 (see ANNEX 1).
- Go through all steps on the list.
- Note and comment on each part.
- Emphasize on the studies with problems.
- Check if all documents are labeled and kept in the right order for easy and quick search.

- Check for any missing or disorganized records.
  - Background and training records of AAERC members
  - Application Submission Records
  - Protocol Assessment Records
  - Communication Records
  - Amendment Approval
  - Meeting Agenda, Minutes, Action letters
  - Active files
  - Continuing and Final reports
- Reserve a meeting room and all necessary facilities.
- Review the AAERC SOPs.
- Make sure that no omission or deviation exists.
- Make sure to have good reasons for any omission or deviation.
- Inform the AAERC members about the inspection date if they are able to attend the audit/inspection meeting.

5.3. Welcome Auditor / Inspector

- The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room.
- Members and some key staff must also be present in the meeting room.
- The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data are needed.
- Answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the point.
- Find and get all information and files requested by the auditors/inspectors.
- Take note of the comments, recommendation of the auditors/inspectors.

5.4. Correct the mistakes

- Review comments and recommendations of the auditors/inspectors.
- Write a report and have it approved by the Chairperson.
- The Chairperson calls for the correction.
- Allow appropriate time for correction and improvement process.

- ❖ Carry an internal follow-up audit.
- ❖ Evaluate the outcome.
- ❖ Report the outcome to the Chairperson.

5.5. Record the Audit/Inspection Event

- ❖ Keep record of the report on the audit/inspection meeting in the audit/inspection file.
- ❖ Record also the findings from the internal follow-up audit in the internal audit file.

6. Glossary

Audit	A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements
Inspection	The act by a regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities

7. ANNEX

ANNEX 1 AF 01-027 Audit and Inspection Checklist

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. World Health Organization, Surveying and Evaluating Ethical Review Practices, Feb. 2002

ANNEX 1 Audit and Inspection Checklist

Audit and Inspection Checklist

ANNEX 1
AF 01-027

☐ Internal Audit ☐ External Audit ☐ Inspection	Date:
The date(s) which the audit/inspection has been agreed for:	
Will an interpreter be required? If yes, what arrangement has been made?	☐ Yes …… ☐ No
Review the SOPs and note details of any omissions or deviations, with reasons	
Check the files for the presence of all signed documents. Note any that are missing and actions taken. ❑ Background and training records of AAERC members ❑ Application Submission Records ❑ Protocol Assessment Records ❑ Communication Records ❑ Amendment Approval ❑ Meeting Agenda, Minutes, Action letters ❑ Active files ❑ Continuing and Final reports	
Are any documents known to be missing from the study master file?	
Which personnel and members will be available? Give details of times and dates.	
What arrangements are there in the event the auditor/inspector needs to make copies of documents?	
Completed by:……..	Date:……..

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1 Purpose

This standard operating procedure (SOP) describes the process for reviewing research protocols that involve storage of specimens beyond the termination of the proposed study and utilization of specimens that have been stored at or with AHRI/ALERT with stored samples as an integral part of their study. The SOP will provide clear guidance in storage of specimens after the study period and its protection and appropriate use of the stored specimens (also called bio data, repositories, gene bank or biobanks) and give guidance for future use of stored samples and associated data.

The use of human tissue materials in combination with information about disease history and life style in biomedical research has attracted a lot of interest by biomedical scientists, philosophers, lawyers and different regulatory bodies. The greatest challenge of biobank includes the lack of participant protection and risk of uncontrolled use of biological samples or related genetic data. On the other hand, biobanks have become strategic and essential tools in research efforts for identification and validation of surrogate biomarkers by collecting, authenticating and preserving human and/or microbial specimens for research purposes, a large number of research efforts are increasingly oriented towards identification of biomarkers with potential application in vaccine development, diagnostics in latent or active disease, prognostic tools of severity of disease and response to therapeutic regimens. This SOP will serve as a practical guideline based on international principles and experiences of developing countries. Until a national guideline is established in Ethiopia to guarantee the protection of research participants and establish harmonized guidelines for the management of biobanks in medical research, it falls upon the individual research ethics committee (RECs) confronted with the task of reviewing such protocol requests by investigators. This SOP offers a practical solution on a day-to-day basis for the AAERC, as well as investigators by ensuring the protection of all participants who altruistically donate their samples to generate and improve knowledge for better diagnosis and medical treatment.

2 Scope

The SOP applies to all research protocols that involve storage of specimen after the study period and use of previously stored data and specimens. It will also help ethical review of research that employ utilization of stored specimens and linked archived data.

3 Responsibility

AAERC chairperson, AAERC administrative staff and the AAERC members will be responsible for implementing this SOP on utilization of stored specimen and linked data.

3.1 Ownership of stored specimens and linked archived data

The AHRI/ALERT will be the owner of all leftover, stored human and biological specimens and their derivatives collected in duly approved research projects along with the data (i.e repositories or biobanks, as both specimens and the linked archived data). However, if an investigator requests to access and use another institute's stored specimens and/or linked archived data, the AAERC will ensure that the relevant sharing agreement entered with the collaborating institute is respected.

4 Flow chart

No.	Activity	Responsibility
1	Receive submitted package	AAERC Secretariat
	↓	
2	Check submitted items	AAERC Secretary
	↓	
3	Review and make decision - Request for storage of biological specimens - Use of linked archived data - Use of stored specimens - Biobank (see Annex)	AAERC members
	↓	
4	Communicate decision	AAERC Secretariat
	↓	
5	Biobank sharing and dissemination through ensuring anonymity of data from biobanks	Investigators, AAERC and collaborating institutes

5 Detailed instruction

5.1 Receive submitted package

- ❖ Receive the application documents submitted by investigators
- ❖ Get contents of submitted package (checklist) form, AF 01-007 (see Annex 1of SOP# AA 007), to check items received
- ❖ Stamp the receiving date on the letter and the documents
- ❖ Sign and date an acknowledgement form upon receiving the packages

5.2 Check submitted items

- ❖ Use the checklist for contents of a submitted package, form AF 01-007(ANNEX 1)
- ❖ 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 Protocol-Related Documents

5.3 Review and make decision

- ❖ Use the Assessment Form (AF 01-008 in SOP# AA008) to guide the review and deliberation process
- ❖ Consider the following criteria when performing the review:

5.3.1. Reviewing protocols involving request for storage of biological specimens and/or linked archived data

Before utilization and storage of biological specimens and/or linked archived data, a separate informed consent (different from that used for enrollment of research participants into the currently proposed study) should be provided by the investigators. This informed consent should describe

- ❖ The purpose of sample storage
- ❖ Quantities of samples to be stored
- ❖ Place where samples will be stored
- ❖ Duration of storage
- ❖ Measures to protect confidentiality
- ❖ Policies that will govern use of the samples in future research

- ❖ Potential risks and benefits of storing samples for future research and
- ❖ Any other information deemed necessary by AAERC

The informed consent needs to clarify to the study participants that they have a free option to decide whether their samples may or may not be stored for future studies.

During utilization and storage of biological specimens and/or linked archived data, the biological specimens need to be strictly anonymized and coded.

5.3.2. Reviewing protocols involving utilization of stored specimens

AAERC after consulting with the relevant national regulatory body on data/specimen repositories shall evaluate the proposal using the following criteria;

I. Determine whether the informed consent under which the specimens or data was collected is adequate to cover their use in the proposed study
II. Determine whether the donors of the specimen are traceable/identifiable
III. Determine whether the repository administrators can effectively anonymize the specimens/data before sending them to the investigators and indeed, if the data that the investigator is going to receive is effectively anonymized
IV. Determine whether use of the specimens will offer extra risk to specimen donors
V. Determine if the proposed study involves genetic studies. If the study involves genetic study, the AAERC will require separate consent for genetic testing and perform mutation analysis on the donated specimens and also follow the national research ethics review committee (NRERC) guidance
VI. Determine whether it is possible to carry out the research without waiving the informed consent

5.3.3. 5.3.3 Reviewing protocols involving utilization of archived data or documents linked to stored specimens

When the data sets are publicly available, their use is exempted. But if the existing data contains identifiable private information, the research will require approval from the AAERC following full board review. In cases of identifiable private information, AAERC must determine whether the information can be used without additional informed consent from the participants.

I. In making this determination, the AAERC shall first examine the conditions of informed consent under which the data were originally obtained. It may be that the proposed research is permissible under the original terms of informed consent.

II. If this is not the case, then the AAERC will consider whether it is permissible to waive the usual informed consent requirements in accordance with stipulated guidelines. Many Often times, a waiver of consent will be appropriate.

III. In other cases, the AAERC may determine that the research can proceed only if the investigator obtains and uses "anonymized" data. Under this scenario, codes and other identifiers are permanently removed from the data set before the data are sent to the investigator, and the removal is accomplished in such a manner that neither the investigator nor the source maintaining the data set can re-establish participants' identities.

IV. However, retrospective studies using existing materials occasionally entail minimal risks and require review by the convened AAERC meeting (e.g., where the research reveals previously undisclosed illicit behavior such as prostitution, drug abuse or where the expedited review had concerns about infringement of subjects' privacy and/or the adequacy of confidentiality protections proposed by the investigators).

5.4 Communicate decision

- ❖ Obtain and complete the appropriate forms, after a decision has been reached by the AAERC.
- ❖ Get signature from the Chairperson
- ❖ Date the form
- ❖ Send letter of approval within seven working days after approval

5.5 Biobank sharing and dissemination

Facilities or institutions that collaborate with AHRI/ALERT on matters involving specimen storage and utilization are advised to have a policy regarding the use of stored samples.

The policy is supposed to cover the following components of biobanking activities:

a. Identity of the collectors of data or tissue samples;
b. The bank/repository storage and data management center;
c. The sharing of data i.e. recipients of the data and
d. Considerations of intellectual property rights

AAERC shall oversee all the activities involved in the above elements such as setting the conditions for collection, securing storage, maintenance and appropriate sharing of the data and/or tissues or intellectual property with external investigators. AAERC reviews and approves the material transfer agreements (MTA) that governs the conditions for the transfer and use of the samples by a recipient partner. The MTA ensures that these documents specify the terms in which samples have been procured and the conditions and obligations under which the recipient will be able to use them. It is the responsibility of

AHRI/ALERT to make sure that the transfer of materials (specimens) from the repository or bank to the recipient is through a formalized MTA signed by both parties. AAERC should examine the MTA in detail for the terms, preconditions set in the document for further utilization of specimens transferred to a recipient institution and agreed between the two partners (the provider and recipient). The specific details of the MTA should include, among other things, purpose for the transfer/export, clear arrangements for collaboration and benefit sharing, a framework for accessing and sharing data, restrictions to third party transfer, and annual reports to the host institution on the status of the samples. Even in the presence of a given MTA, the provider institution should provide consent to the recipient on further utilization of the materials or their derivatives transferred through the original MTA. In addition, it should also be the responsibility of the investigator to inform the AAERC on any deviations from the MTA by partners.

6 Glossary

Anonymity

This decision on anonymity of data depends on the probability that a specific individual cannot be identified from the information. Equally important is that identifiable information is dependent on both the amount of information held and, on the skills, and technology employed by the holder. Separation between non-identifiable and identifiable data is thus technology and information based but is also highly dependent upon the ethical conduct, adherence to good governance practices and an understanding of the duties owed, by custodians and responsible officers, in relation to the biobanks, associated data and other databases. The

concept of personal or identifying information is better viewed as a spectrum or continuum from identified to non-identified.

Associated data

Is a personal, clinical, biochemical, genetic and phenotypic information about the participant.

Biobank (Biorepository, Genebank)

Is systematic collection and storage of human biological material (Sample/Specimen) and any related information (linked archived data) deposited for long period in a centralized system with sharing arrangement

Custodianship of a biobank

Is an individual or agency nominated to be responsible for the actions of the biobank. This incorporates the authority to access, use and destroy the samples and data held. The biobank custodian is considered to be either, an individual researcher, chief executive, executive director of relevant institute, head of department, or the department or institute responsible for creating the biobank. It implies that the bank will guarantee the safe and ethical handling of the specimens, as well as the proper use and optimal sharing with researchers and eventually safe disposal.

Human Biological Material

Is a biological material collected from an individual at the time of inclusion in the biobank (e.g. blood, urine or tissue sample) or derived from material collected (e.g. DNA extracted).

Identifying information (identified)

Is information where the identity of an individual is apparent or can reasonably be ascertained by the holder of the information. Information that may directly, or indirectly, lead to identifying individuals from whom the samples and associated information are collected as a link (or multiple links) exists between the participant's personal identifiers and the data.

Long term sample storage

Is a process of containing biological sample after the study period with the intention of future reuse by investigator or the institute but not shared with centralized

storage like biobanks. When and how the sample reused may not be specified as the purpose and date not yet established.

Material Transfer Agreement

is generally signed between a provider and a recipient, used to document the transfer of materials, with or without information, either to an entity (i.e. the recipient) and/or away from an entity (i.e. the provider) and is subject to a number of terms and conditions.

Non-identifiable information

Is in which the holder of the information cannot reasonably ascertain the identity of a specific individual. This includes information that has never been labeled with individual identifiers or from which they have been permanently removed.

Sample

Is a single unit obtained from one individual or a single unit of human biological material collected or derived from material collected (refer to the definitions for specimen and human biological material).

Specimen

Is a specific collection of tissue, blood or urine taken from a single individual at a specific time.

7 Annex

7.1. Biobank (preliminary SOP)

I. Establishment of biobanks

a. Consult the national guideline if any
b. The initiators or custodian should develop criteria for sampling and participant selection to ensure data are representative of the targeted population.
c. The biobank should have a business plan.
d. Consultations should be carried out with diverse stakeholders, groups and communities. The initiators or the custodian should clearly indicate to those consulted how their input may influence the establishment and/or future aims of the biobank.
e. The biobank custodian should ensure information on the biobank is made publicly available and easily accessible to stakeholders, including participants and the general public.

II. Terms of participation

a. Prior to requesting signed consent the biobank custodian should ensure participants are provided with detailed information.

b. The biobank custodian should ensure there are policies on participation.

III. Content of biobanks

a. The biobank custodian should ensure there are policies on contents.

b. The biobank custodian should ensure it is specified which type of data and samples will be collected.

c. This should be justified on the basis of the scientific objectives and purposes of the biobank.

d. The biobank should have a quality management process that maintains participant confidentiality.

e. The biobank's holdings should be maintained through a system that allows all the biological material, data and any other information to be tracked.

f. The biobank custodian should ensure the OECD Best Practice Guidelines for Biological resource centers or other appropriate guidelines are followed.

IV. Protection of human biological materials and data

a. The biobank custodian should ensure privacy and confidentiality is protected through a combination of mechanisms as appropriate.

b. The biobank custodian should ensure that the data contained within the biobank databases are protected in accordance with domestic law.

c. Data protection should where appropriate involve the separation of information that can readily identify an individual from other data (e.g. genotypic data).

d. The biobank custodian should ensure a robust infrastructure is in place consisting of both hardware and software components, to prevent unauthorized access.

e. The biobank custodian should ensure only a restricted number of authorized staff has access to information identifying or potentially identifying participants and that this is monitored and documented.

f. The biobank custodian should ensure there are policies on protection.

8 References

1) Armauer Hansen Research Institute /All Africa Leprosy TB Rehabilitation and Training Centre Ethics Review Committee (2009), Standard Operating Procedures, 2nd ed. Addis Ababa, Ethiopia
2) Human Tissue Authority; Code of Practice (2006)
3) Human Tissue Act (2004)
4) Department of Health WA (2010), Guidelines for human biobanks, genetic research databases and associated data, Office of Population Health Genomics Public Health Division
5) Makerere University College of Health Sciences School of Medicine (2010), SOP for Review of Research Using Patients Stored Data and Specimens, SOP 006

Table Of Contents

1. **Purpose**

The purpose of this SOP is to provide criteria for determination of which study protocols can be exempted by providing exemption number for better management of exempted protocols

2. **Scope**

This SOP applies to the review and approval of studies based on information already available in the public domain or undergraduate studies proposed only for academic exercise, despite involvement of human participants. However, studies involving human subjects with an intention to use the data beyond academic exercise cannot be exempted.

3. **Responsibility**

It is the responsibility of the Chair and secretariat to define of which study protocols should be exempted.

4. **Flow chart**

No.	**Activity**	**Responsibility**
1.	Receive the submitted documents.	AAERC Secretariat
	↓	
2.	Determine protocols for exemption	AAERC Secretariat/ Chairperson
	↓	
3.	Assign exemption number	AAERC Secretariat
4.	Communicate with the AAERC and the Investigator.	AAERC Secretariat

5. **Detailed instructions**

5.1. ***Receive submitted documents.***

- Receive the application documents submitted by investigators.
- Get contents of submitted package (checklist) form, AF 01-007 (see Annex 1 of SOP# AA 007), to 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 AAERC secretariat.

5.2. ***Determine protocols for exemption.***

- ❖ AAERC Chair with secretariat determines whether a study is qualified for exemption according to the following criteria:

5.2.1. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available and recorded without identifiers.

5.2.2. Evaluation or examination of government projects or programs designed to explore public benefit or service programs; procedures for obtaining benefits or services under those projects or programs; possible changes in or alternatives to those programs or procedures.

5.2.3. Quality assurance activities.

5.2.4. Studies conducted by a group of students for exercising research methods provided there is no direct contact with participant or research participants cannot be identified

5.2.5. Survey protocol of National or local survey and census

- ❖ If the protocol satisfied any of the criteria for exemption, the secretariat will send the protocol to Chairperson.

5.3. ***Exemption Process***

- ❖ Chairperson determine if the protocol qualify for exemption
- ❖ The Chairperson communicate the decision.
- ❖ The secretariat document exemption number
- ❖ The secretariat will communicate to the investigator/s the decision of exemption and the requirement of final report
- ❖ Inform the AAERC of the proposals exempted at its regular meetings.

6. **Glossary**
7. **References**

National Research Ethics Review Guideline. Addis Ababa, Ethiopia. 5th ed., 2014

8. **Annex**

Table Of Contents

1.Purpose

This SOP provides guidance regarding definition of terms, abbreviations and titles used by the AHRI/ALERT Ethics Review Committee (AAERC) and its administrators to facilitate use and understanding of the AAERC Standard Operating Procedures and activities

The definitions are divided into two sections:

- ❖ Description/definition of individual roles as used in the AAERC SOPs
- ❖ Description/definition of terms and abbreviation used in the AAERC SOPs

2. Scope

This section applies to all AAERC SOPs and activities in addition to persons preparing and/or using the SOPs.

3. Responsibility

It is the responsibility of the AAERC members to define or determine and approve the appropriateness of the description.

4. Flow chart

No.	Activity	Responsibility
1.	Description of individual titles and roles	AAERC members and Secretariat
2.	Definition of terms	AAERC members and Secretariat
3.	Addition / Correction of new titles and terms	AAERC members and Secretariat
4.	Approval of the new addendum	AAERC members / Chairperson

5. Detailed instructions

5.1.Description of individual roles

Chairperson:

A member of the AAERC who presides over a board meeting Is responsible for expedited approvals on behalf of the Board

Coordinator (Site):

The person at the study site who is responsible for managing the study The Principal Investigator can also be the site coordinator and manager

AAERC

The AAERC is a body established to review and monitor biomedical research involving human subjects. The primary purpose of such a review is the protection of the rights and welfare of the human subjects. In accordance with applicable national/international regulations, the AAERC has the authority to approve, require modifications to, or disapprove research.

The AAERC consists of a review board with at least five regular members in addition to alternate members. Alternates are categorized and given equal status as regular members within the board (i.e., non-scientific or M.D, etc.). The composition of the membership must reflect a diversity of backgrounds sufficient to assure:

- expertise and experience to provide adequate review of research activities
- consideration of race, gender, and cultural backgrounds
- sensitivity to attitudes and concerns of the community and the patient population
- knowledge of applicable regulation, laws and standards of professional
- conduct and practice
- no member participates in the review process of any study project in which he/she has a conflicting interest
- no gender discrimination

Biobank (Biorepository, Genebank)

Biobank is systematic collection and storage of human biological material (Sample/Specimen) and any related information (linked archived data) deposited for long period in a centralized system with sharing arrangement.

AAERC Members

Non-employee individuals serving as regular and alternate members on AHRI/ALERT ERC (i.e., the AAERC membership). Employees of AHRI/ALERT may serve as members of the AAERC in their capacity as experts with the primary purpose of their membership in the AAERC being human participant protection. The Director of AHRI/ALERT will be a member of the AAERC. He/She will take responsibility to

ensure that the administrative requirements for the services of the AAERC are handled by the Institute.

The AAERC is constituted in accordance with the AAERC membership requirements, and individuals are qualified to vote at a duly convened AAERC meeting.

Exemption

Although the category is called "exempt," this type of research does require AAERC review and registration. The exempt registration process is much less rigorous than an expedited or full-committee review. To qualify, research must at least be based on information already available in the public domain or proposed for education purpose. For more details, refer the National Health Research Ethics Review Guideline, Section 7.2, 5th ed. 2014.

Investigational New Drug (IND)

Investigational new drug means a new substance, antibiotic drug, or biological product that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms “investigational drug” and “investigational new drug” are deemed to be synonymous for purposes of this part.

Non-Local AAERC Review

Under certain circumstances, local review by an Institutional Review Board may not be available, e.g., research conducted by investigators affiliated with an institution without an IEC/ERC. Local regulatory agencies such as Drug Administration and Control Authority (DACA) may allow review of research by the AAERC in locations other than where the research is to be performed. Therefore, the AAERC may review studies that are not performed on-site as long as the requirements are met.

Principal Investigator

Individual responsible for implementing and coordinating an investigational Study.

Secretariat

The AAERC staff who are responsible for the day-to-day administrative functions and

duties which support the activities and responsibilities of the ERC members.

SOP Team

A selected group of the AAERC members and administrative staff who oversee the preparation, review and periodic revision of the AAERC SOPs

Vice Chairperson

A member of the AAERC who assists the Chairperson as needed in conducting meetings and expedited review

Vulnerable subjects

A category of research participants that includes children, prisoners, pregnant Women, handicapped or mentally disabled persons and economically or educationally disadvantaged persons who are likely inclined to coercion or undue influence

5.2 Definition of Terms

Active study files

Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the AAERC

Administrative documents

Documents include official minutes of Board meetings as described in SOP, The AAERC meeting minutes and voting records and the standard operating procedures, both historical files and Master Files as described in the SOP, SOP distribution, implementation and file maintenance.

Deviation

Any instance in which the current approved AAERC SOP cannot be or has not been followed.

DSMB

For human intervention studies, a Data Safety Monitoring Board (DSMB) will be established according to WHO/TDR guidelines for DSMBs.

Expedited approval

An AAERC approval granted only by the Chairperson of the AAERC or a designated AAERC member (not the full Board) for "minor" changes to current AAERC-approved research activities and for research which involves no more than minimal risk

Final report

An obligatory review of study activities presented as a written report to the AAERC after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution.

Complete, comprehensive written description of a completed trial that describes the experimental materials and statistical design, presentation and evaluation of the trial results and statistical analyses

Historical file

A document file which was effectively used in the past and presently became obsolete or expired, but still had to be kept in a file for reference purposes.

Inactive study files

Supporting and approved documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communication and correspondence with the investigator, and reports (including but not limited to progress reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the AAERC for which a final report has been reviewed and accepted in active study files are archived for a minimum of three years following the completion of the study. These files can be retrieved as needed.

Investigational medical device

A medical device which is the object of clinical research to determine its safety or effectiveness

Master files

Original copies of documents such as SOPs, guidelines, instruction, manual with real signatures of preparers, reviewers and authorized persons are systematically stored in secured cabinets with limited access.

Medical Device

A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kids for in vitro diagnosis of disease and other conditions, (for example, pregnancy).

Minutes

The official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) independent board review meeting. The minutes identify fully each protocol and/ or activity and record the outcomes of each voting action. The board votes separately on each collective set or each item submitted for review: protocol, consent form, investigator, and advertisement(s). The record notes the number for, number against, the number of abstaining votes, and the reason for the abstention(s), without identifying the individual member's names.

New Study

A study protocol including the informed consent, investigator's qualifications, information on the drug or device and advertisements (if applicable) presented to the AAERC for approval for the first time and not previously approved by the Committee. This includes re-application for those studies denied approval by the AAERC

Non-compliance record

A list containing the identity of investigators who are considered by the AAERC to be non-compliant with national/international regulations or who fail to respond to the

AAERC's requests, and the incident(s) justifying the reason for the determination of non-compliance

Non-significant Risk Device (NSR)

A non-significant risk device is an investigational device that does not pose a significant risk.

Progress Report

An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the AAERC. Generally, these reports are due annually with the AAERC sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the AAERC.

Protocol Amendment

A change to the study protocol during the planning or course of the trial The amendment is a foreseen change to the study plan that requires formal approval by the sponsor.

Quorum

Attendance required to arrive at a decision at any convened meeting of the ERC. If 5 is the minimum number of members prescribed in the SOP, 3 of the regular (or alternate) members, including at least one physician and one layperson constitutes a quorum and should be maintained throughout the discussions and voting portions of the meeting.

Significant Risk Device (SR)

A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject, (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the subject, (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the subject, or

(4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participants.

5.3 Addition / Correction of terms

- ❖ Members are encouraged to propose any additional terms or make correction of any terms defined in this SOP at any time, if he/she feels clarification should be made.
- ❖ Write your proposal.
- ❖ Submit your proposal to the AAERC secretariat.

5.4 Approval of the addendum

- ❖ The AAERC secretariat shall bring the proposal to a meeting.
- ❖ The proposal shall be discussed for further opinion.
- ❖ Agreement and approval shall be made at the meeting.

6. Glossary

7. ANNEX

8. Reference

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Operational Guideline for the Establishment and Functioning of Data and Safety Monitoring Board (www.who.int/tdr/publications/publications/pdf/operat_guidelines.pdf)

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