Ethiopian Association of Anesthetists

Institutional Research Ethics Review Committee

Application Guide for researchers

November 2023

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Introduction

Welcome to the application guide for the Ethiopian Association of Anesthetists Institutional Research Ethics Review Committee (EAA IRERC). This guide is designed to provide comprehensive information and instructions for researchers who wish to submit their research proposals for evaluation and approval by the EAA IRERC. The EAA IRERC was established with the aim of ensuring that all research activities conducted within the field of anesthesiology in Ethiopia adhere to the highest ethical standards. As an esteemed organization, EAA IRERC prioritizes the protection of participants' rights, safety, and well-being. By following this guide, researchers will be equipped with the necessary knowledge and requirements to navigate the application process smoothly. Whether you are a seasoned researcher or new to the field, we are committed to supporting your research endeavors and contributing to the advancement of anesthesiology in Ethiopia.

Type of submission

The types of submission for an Institutional Review Board (EAA IRERC) are as follows:

1. **Initial Review:** This type of submission is made when a researcher submits a new research protocol to the EAA IRERC for review and approval before starting the study. It includes all the necessary documents and information related to the study's design, potential risks, benefits, and participant protection measures.

2. **Resubmission for Re-review:** In case the initial review results in some concerns or minor revisions requested by the EAA IRERC, a researcher may need to make necessary changes and resubmit their protocol for re-review. This resubmission ensures that any requested modifications or clarifications have been adequately addressed.

3. **Protocol Amendments:** If a researcher needs to make significant changes to an already approved research protocol, an amendment submission is required. These changes could include modifications to the study design, recruitment methods, informed consent process, or other aspects that may impact participant safety or study integrity.

4. **Continuing Review of Approved Protocols:** Research protocols approved by the EAA IRERC have an expiration date and need to undergo periodic review to ensure ongoing compliance with ethical and regulatory standards. Researchers are required to submit a continuing review application providing updates on study progress, any adverse events, and any other relevant information to demonstrate that the study remains ethical and justified.

5. **Protocol Termination:** If a researcher decides to end a study prematurely or if the EAA IRERC determines that a study needs to be terminated due to safety concerns or ethical issues, a protocol termination submission is made. This notifies the EAA IRERC of the decision to end the study and includes an explanation for the termination.

It's important to note that specific submission types and processes may vary in EAA IRERCs, so it is recommended to refer the EAA IRERC specific guidelines and requirements. *(For More information - irb@eaansa.com)*

Flow Chart for Protocol Review

EAA-EAA IRERC-SOP/AF/01-009/02.0

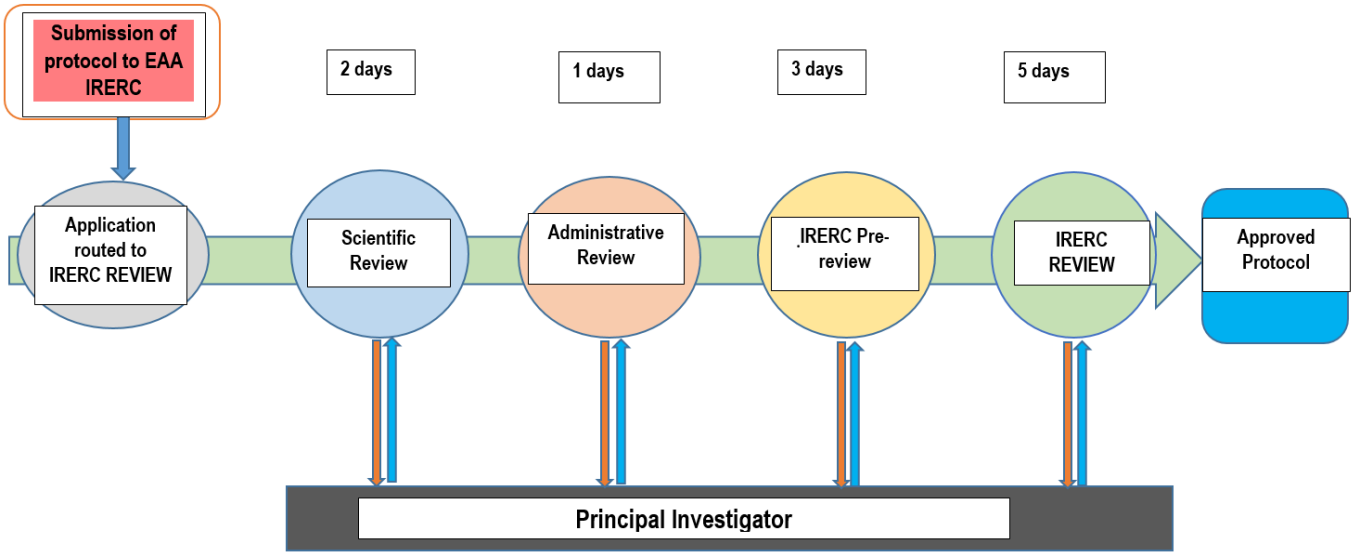

Figure: EAA IRERC Protocol Review Process map

Submission of Initial Application form

"EAA-EAA IRERC-SOP/af/01-009/01.0," Need to be digitally submitted (Link _) (Annex 1)

The provided application form, "EAA-EAA IRERC-SOP/af/01-009/01.0," is for protocol submission to the EAA IRERC (Institutional Research Ethics Review Committee). This form is used to provide detailed information about the study protocol. Here is a breakdown of each section within the form:

- Protocol Title: This is where the title of the protocol should be mentioned.
- Protocol Number: This field will be provided by the EAA IRERC.

- Total Participants to be Included: Specify the total number of participants intended for the study.
- Study Type: Checkmark the applicable study type(s) from the options provided, including survey - social, medical, community-based, individual-based, screening - observational, epidemiology, intervention study, clinical trial (phase I, II, III, IV), or genetic study (retrospective, prospective, or specify others).
- Study Population: Specify the characteristics of the study population, such as healthy, patient, or vulnerable groups.
- Characteristics of Participants Participated: Specify the age range of participants involved, pediatric details (if applicable), and impaired characteristics (physically, cognitively, and mentally).
- Requested Exclusion of Participants: Specify any requested exclusion of participants, such as male, female, children, or specify others.
- Special Resource Requirements: Checkmark any special resource requirements needed for the study, such as intensive care, isolation unit, surgery, pediatric intensive care, transfusion, cat scan, gene therapy, controlled substances, prosthetics, gynecological services, or specify others.
- Ionizing Radiation Use: Specify if ionizing radiation (x-rays, radioisotopes, etc.) will be used in the study or indicate if none.
- Investigational New Drug (IND)/Device (IDE): Specify if an IND or IDE will be used in the study or indicate if none. Provide the FDA numbers, names, and sponsors or holders.
- Procedure Use: Indicate if the procedures used in the study will be invasive or non-invasive.
- Multi-site Collaboration: Specify whether the study involves multi-site collaboration or not.
- Financial Disclosure: Specify if there are any financial disclosures associated with the study.
- Institute Research Contact: Provide the name, address, telephone/fax numbers, and email of the institute research contact.
- Participating Investigators: Provide the names, license numbers, institutions, and telephone/fax numbers of the participating investigators.
- Type of Review: Checkmark the appropriate type of review, such as initial, resubmission, amendment, expedited, emergency, continuing, report, or protocol termination review.
- Signatures: The principal investigators and the protocol chairperson (if applicable) should sign and date the form.
- Completion: Provide the date of completion and application number.

Please note that this explanation provides a general understanding of the form and its sections. For accurate interpretation and submission, it is essential to refer to the official guidelines and instructions provided by the EAA IRERC.

Executive Summary Form –

Need to be digitally submitted (Link _)

The EAA-IRERC Executive Summary Form is a document used by the Ethiopian Association of Anesthetists Institutional Research Ethics Review Committee (EAA-IRERC) to summarize research proposals that require initial review. This form, typically 1-2 pages in length, follows a specific format and includes essential information about the proposed project.

The Executive Summary begins with the project title and lists the investigators involved, including the Principal Investigator (PI) and Co-PI if applicable. It also includes details about the project's sponsor or funder.

The Background/Rationale section provides a brief explanation of the research question that will be addressed in the proposal. This section highlights the necessity of the research and explains its relevance. It may also reference relevant and recent studies that support the research topic.

The Objective section outlines the specific goals or objectives of the study. It may include information about the study site(s) and design, study duration, study population, sample size, and eligibility criteria such as inclusion and exclusion criteria, age, gender, and other relevant factors. Furthermore, the Data Analysis section briefly describes the planned methods for analyzing the collected data.

The Ethical Consideration subsection emphasizes the importance of ethical principles in conducting the research. It may address areas such as informed consent procedures, privacy protection, and safeguards for vulnerable populations.

The Executive Summary form may also include an Expected Outcome section, where the anticipated results or impact of the research project are briefly summarized. Moreover, a Budget section might be included to outline the estimated financial resources needed for the research.

EAA-IRERC Executive Summary Form serves as a concise yet comprehensive overview of the proposed research project, allowing the committee to assess the project's relevance, feasibility, and ethical considerations.

Document Receipt Form: EAA-EAA IRERC-SOP-AF/02-007/01.0

Need to be received by the researcher from EAA IRERC

The Ethiopian Association of Anesthetists Institutional Research Ethics Review Committee (EAA-IRERC) Document Receipt Form (EAA-EAA IRERC-SOP-AF/02-007/01.0) is a standardized form used to track and record the receipt of important documents related to research protocols submitted for review by the committee.

The form includes various fields to capture relevant information including the received number, protocol number, submitted date, type of submission (initial review, re-submission for re-review, protocol amendments, continuing review), protocol title, principal investigator's details (name, telephone number, fax, e-mail, preferred contact method), and institute details.

Additionally, the form provides different options for the delivery route of the submitted documents (post, e-submission, in-person). There is a section to indicate whether the documents submitted are complete or incomplete, with a provision to specify the date for submitting the remaining documents later.

Furthermore, the form includes checkboxes for various documents that are typically required for research protocols, such as information for subjects, informed consent form, case report forms (CRF), study budget, investigator's brochure, and others. There are checkboxes to indicate whether these documents are included with the initial submission or if they will be submitted later.

EAA-IRERC Document Receipt Form serves as a systematic way for the committee to keep track of the received documents, ensure compliance with the required paperwork, and facilitate efficient communication with the principal investigators throughout the review process.

EAA IRERC Protocol adherence checklist

The protocol summary sheet or memorandum is a concise document that provides an overview of a study protocol. It serves as a checklist to ensure that all necessary information and components of the protocol are included. Here is a breakdown of the sections to check for inclusion:

1. Title of the protocol: The summary sheet or memorandum should clearly state the title of the protocol, providing a succinct description of the study.
2. Principal investigator: The name and contact information of the principal investigator responsible for conducting the study should be listed.

3. Sponsor: The entity or organization sponsoring the study should be clearly identified.
4. Abstract: A brief summary or abstract of the study should be included, outlining the key objectives, methods, and expected outcomes.
5. Type of protocol: The summary sheet should specify the type of protocol being employed, such as screening, survey, clinical trial, or a specific phase of clinical trials (e.g., Phase I, II, III).
6. Objectives: This section should outline the main goals and research questions that the study aims to address.
7. Anticipated outcome: The summary sheet should briefly describe the expected results or outcomes of the study.
8. Inclusion/Exclusion criteria: The criteria for selecting participants or subjects should be clearly stated, highlighting the characteristics that make individuals eligible or ineligible for the study.
9. Withdrawal or discontinuation criteria: Any conditions or circumstances that may lead to participant withdrawal or study discontinuation should be outlined.
10. Modes of treatment studied: If the study involves different treatment arms or interventions, this section should outline the specific modes of treatment being studied.
11. Methodology: A synopsis of the study design should be included, describing the overall research approach and methodology.
12. Analysis methods: This section should briefly describe the statistical or analytical methods that will be used to analyze the study data.
13. Activity plan/timeline: The summary sheet should provide a general timeline or plan of activities, outlining the key milestones or stages of the study.
14. Schedule and duration of treatment: The summary sheet should specify the treatment schedule and the planned duration of treatment for participants.
15. Efficacy or evaluation criteria: The criteria for evaluating the efficacy or effectiveness of the treatment should be mentioned, including any specific response or outcome measures.
16. Safety parameters criteria: The summary sheet should highlight the criteria or parameters used to assess the safety of the treatment, particularly in terms of potential toxicity or adverse events.

By checking for the inclusion of these sections, the summary sheet or memorandum ensures that all essential information about the study protocol is compiled in a concise and organized manner.

Annex

Annex 1: Initial Application Form

EAA-EAA IRERC-SOP/AF/01-009/01.0

Protocol Title:	
Protocol number: (To be provided by EAA IRERC)	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	☐ None	☐ 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/Psychotropic)

☐ Prosthetics ☐ Gynecological services ☐ others, specify…….

☐ Organ transplantation, specify…… ……..

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

☐ None ☐ medically indicated only

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

☐ None ☐ IND ☐ IDE

FDA No: …… FDA No: ……

Name: …… Name: ……

Sponsor: ……. Sponsor: ……...

Holder: …… Holder: ……...

PROCEDURE USE: ☐ Invasive ☐ Non-invasive

MULTI-SITE COLLABORATION: ☐ YES ☐ NO

FINANCIAL DISCLOSURE: ☐ YES ☐ NO

INSTITUTE RESEARCH CONTACT

Name: ……

Address: ……

Telephone: ……

Fax: ……

E-mail: ……...

Participating Investigators			
First / Last Name	License No.	Institution	Telephone / Fax No.
1.			
2.			
3.			
4.			
5.			

Type of review:

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

SIGNATURES:

Principal Investigators Date: ……

Protocol Chairperson (if applicable) Date: ……..

COMPLETION:

Date: ……

APPLICATION NUMBER : ☐☐☐ / ☐☐ - ☐☐

Annex 2: Checklist: Protocol Summary Sheet Adherence Checklist

Check the Summary Sheet or Memorandum of the study protocol for inclusion of the followings:

S.NO	Sections	Yes	No
1.	Title of the Protocol		
2.	Principal Investigator		
3.	Sponsor		
4.	Abstract		
5.	Type of Protocol (screening, survey, clinical trial and phase)		
6.	Objectives		
7.	Anticipated Outcome		
8.	Inclusion/Exclusion Criteria		
9.	Withdrawal or discontinuation Criteria		
10.	Modes of Treatment Studied		
11.	Methodology (synopsis of study design)		
12.	Analysis (methods)		
13.	Activity plan / Timeline		
14.	Investigational New Drug (IND) Number (if applicable)		
15.	Schedule and Duration of Treatment		
16.	Efficacy or Evaluation Criteria (Response/Outcome)		
17.	Safety Parameters Criteria (Toxicity) (If needed)		

Annex 3: Initial Review Submitted Package Adherence Checklist

EAA-EAA IRERC-SOP-AF/01-007/01.0

Protocol Number: _____

S.No	Components	# Copies	Yes	No	NA
1.	Protocol Summary Sheet	1			
2.	Original Initial Review Application Form	2			
3.	Office memo or supporting letter	1			
4.	Protocol and Protocol-Related Document				

5.	❖ Informed consent form with information for subjects	1			
6.	❖ Study budget	1			
7.	❖ GCP or research ethics training	1			
8.	❖ Curriculum vitae (CV)	1			
9.	❖ Certificates MoU	1			

Annex 4: Resubmission for Re-review Submitted Package adherence checklist

S.No	Components	# Copies	Yes	No	NA
1.	Resubmission or "Correction" Protocol / Memorandum	1			
2.	Revised Protocol Summary Sheet (if submitted initially)	1			
3.	Original Initial Review Application Form	1			
4.	Protocol and Protocol-Related Documents				
5.	❖ Informed consent form1information for subjects	1			
6.	❖ Study budget	1			
7.	❖ GCP or research ethics training	1			
8.	❖ Curriculum vitae (CV)				
9.	❖ Certificates MoU	1			

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

Protocol Amendment Submitted Package

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

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

Continuing Review Package

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

Final Report Reviewχ

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

Protocol Termination Package

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