RESEARCH OFFICE

AFRICA INTERNATIONAL UNIVERSITY
INSTITUTIONAL ETHICAL REVIEW BOARD
STANDARD OPERATING PROCEDURES

Submitted By:

September, 2017

LIST OF ABBREVIATIONS

AIU:	Africa International University
DVCAAR:	Deputy Vice Chancellor for Academic Affairs and Research
IAC:	Independent Appeals Committee
ICT:	Information and Communication Technology
IERB:	Institutional and Ethics Review Board
M&E:	Monitoring and Evaluation
NACOSTI:	National Commission for Science, Technology and Innovation
PI:	Principal Investigator
SOP:	Standard Operating Procedures
VC:	Vice Chancellor

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INTRODUCTION

1.0 Africa International University is a chartered Christian university located in the serene environment of Karen, a strategic location, serene and conducive for learning. Africa International University currently trains students in Theology, Business, ICT, Psychology, Languages and Education. The following are the University's Vision, Mission and Core Values:

Vision

The Vision of AIU is "Christ-centered leaders in Africa educated to transform God's people and world"

Mission

To accomplish our Vision, we undertake the Mission is to: "educate Christ-centered leaders for the transformation of God's people and world through innovative programs, research, and community engagement"

Core Values

To become the kind of AIU community that God wants and to be relevant to this vision and mission, we need to treasure the right things. The following values, therefore, will be cultivated as we seek to become useful for the mission and vision entrusted to us:

1. Excellence with Relevance – a solutions approach to learning.
2. Faith with Integrity – a discipleship and missional approach to theology and spirituality.
3. Leadership with Servant-hood and Stewardship – leadership that combines deep personal humility and humanity with an unwavering commitment to do the will of God at all costs.
4. Innovation with Community – team-oriented leaders who seek creative and biblical solutions for the common good in their respective areas and callings, not ministry or marketplace "soloists

1.1 In the discharge of its responsibilities, the University collaborates and cooperates with both local and international, and public and private institutions and organizations including Kenya's Ministry of Education, the National Commission for Science, Technology, and Innovation, and Commission for University Education.

1.2 Research and related activities in the University are managed, guided and approved through committees that operate at different levels with the organization.

1.3 The standard operating procedures (SOP) outlined in this document are meant to guide and standardize operations of research and related activities that are internal and external to the University. The SOPs provide guidelines pertaining to ethics and use of human subjects, animals and plants in biomedical research.

1.4 The SOPs capture the spirit of the current research strategic plan and the University's 2030 vision, which endeavors to promote and sustain excellence in research and uphold "best practices."

1.5 This document of IERB SOPs will be reviewed annually, with a summary report written by the IERB Chair. The report is due by May 1st of each year. The IERB Chair shall convene an IERB meeting in April each year, with appointed IERB members, for the purposes of this review.

OBJECTIVES

1.6 The primary objective of the SOPs outlined herein is to provide a consistent and standardized framework for managing, guiding, and approving scientific research and related activities in the University.

1.7 The procedures will guide development, review, approval, implementation and monitoring of research projects. Included in this document are procedures for guiding research collaborations and partnerships, transfer of biological materials, addressing bio-safety issues, handling intellectual property matters, and resolving scientific conflicts.

COORDINATION OF AIU RESEARCH

1.8 Scientific research at AIU is coordinated and managed at the ISAR office.

1.9 AIU IERB Office, located within the ISAR Office, coordinates receiving and screening external and internal research proposals according to SOPs.

1.10 The Institutional Ethical Review Board (IERB) within the ISAR Office:

(i) Guides scientific research.

(ii) Reviews and makes decisions on accepting, requesting resubmission or deferring approval on external and internal research proposals, specifically regarding IERB related practices.

(iii) Ensures compliance with ethical standards of practice in the proposal.

(iv) Provides documentation for approval or request for corrections for resubmission, or deferral of the research proposal.

(v) Monitors compliance of ethical practices during the research process. Monitoring by AIU IERB is contingent upon specific agreements with the Principal Investigator, e.g. once external proposals are approved, AIU IERB may--or may not-- provide monitoring of the actual research process.

1.11 The AIU Institutional Ethical Review Board is located and operated within the ISAR Office under the guidance of the ISAR Director.

1.12 The AIU SOPs outlined in this document pertain to the operations of the AIU IERB only.

INSTITUTIONAL ETHICAL REVIEW BOARD (IERB)

1.13 The Research Office serves as the 'Secretariat' of the IERB, hereafter referred to as the IERB Office.

1.14 The IERB Office provides administrative support to the IERB operations. This includes communicating with parties associated with the IERB functions, and maintaining data on IERB activities. The IERB Office is responsible for electronic filing of approved research proposals, correspondence, and IERB related documents, including both internal and external to the IERB functions.

2.0 The Deputy Vice Chancellor of Academic Affairs (DVCAAR) appoints the IERB committee members.

IERB INFRASTRUCTURE

2.0 The IERB Office is located within the ISAR Office at Africa International University (AIU).

2.1 IERB members shall be appointed for a term of 4 years by the DVCAAR. The term of service may be renewable up to two additional terms, for a maximum of 12 years of IERB membership.

2.2 All AIU IERB primary reviewers will have attended IERB related training and shall be certified to serve as IERB members.

2.3 An IERB Chair and Vice Chair shall be appointed by the Deputy Vice Chancellor of Academic Affairs (DVCAAR) in coordination. The IERB Chair and Vice Chair shall serve for a term of 4 years. The term is renewable one time, for a maximum of 8 years of IERB service.

2.4 A maximum of 21 and a minimum of 6 certified members will make up the pool of IERB reviewers.

2.5 External reviewers, such as laypersons and subject matter experts will be appointed by the DVCAAR as recommended by the IERB committee. A resource list of external reviewers will be maintained by the IERB Office.

2.6 A quorum of 5 certified IERB members are required to transact an IERB review meeting.

2.7 The IERB members will meet on the first Wednesday of every month or as designated by the IERB Chair.

2.8 The IERB Office shall receive incoming research proposals on Mondays of every week, except holidays when proposals will be received on Tuesdays.

2.9 Minutes will be recorded at each IERB meeting.

IERB IMPLEMENTATION, TRAINING AND MONITORING TEAM

2.10 Upon accreditation approval of AIU Institutional Ethical Review Board:

a) A team of a minimum of three (3) IERB members will be appointed by the DVCAAR in coordination with the IERB Chair, to serve as the IERB implementation, training and monitoring team.

   i. The implementation functions shall focus on initial set up and follow up of the IERB functions, according to the approved AIU SOPs.

   ii. The training functions shall include new IERB member certification training, as well as orientation to IERB SOPs. Periodic training workshops shall be held to increase accuracy and performance of IERB SOP compliance.

iii. The monitoring functions shall ensure compliance with day-to-day IERB Office SOP procedures to ensure compliance with established SOP requirements.

iv. The IERB implementation, training and monitoring team shall submit recommendations for IERB improvements to the IERB Chair and DVCAAR, particularly during the first year of implementation of the SOPs.

b) The IERB-Implementation, Monitoring and Training appointed members will serve for one year.

i. An evaluation will be conducted at the end of the first year of AIU accredited IERB. The evaluation will determine if the IERB-IMT shall continue for an additional term or shall be modified to meet any changes during the second year of the IERB accreditation. The evaluation is completed by the IERB Chair in coordination with IERB members, and the DVCAAR

SOP 1: STRUCTURE OF THE IERB-

Offices

The IERB Chair

The IERB Chair must have an in-depth understanding of ethical issues in the conduct of human, animal, and plant research; as well as national policies, laws, and AIU's research policy.

The responsibilities of the IERB Chair shall be:

a. To provide leadership in establishing and implementing guidelines and standard operating procedures for the IERB.
b. To screen all new proposals presented to the IERB Office, and allocate a minimum of three (3) IERB reviewers.
c. To screen and approve requests for expedited reviews.
d. To screen letters of appeal which dispute previous IERB decisions, and request IERB office to schedule review.
e. To assess conflict of interest reported by other IERB members.
f. To ensure that quorum is present and maintained during convened IERB meetings.
g. To ensure that continuing review of research is conducted appropriately and in a timely manner.
h. To direct proceedings and discussion of the full IERB meeting.
i. To represent the IERB in discussing IERB decisions with Investigators.
j. To confirm and sign the minutes for each IERB meeting.
k. To represent the IERB in discussions between AIU-Africa and other institutions.
l. To recommend new and replacement members of the IERB in coordination with the Deputy Vice Chancellor of Academic Affairs (DVCAAR) within AIU.
m. To delegate duties to the Vice-Chair, or to assign the Vice-Chair in the Chair's absence.

n. To serve as a member of the IERB.
o. To present annual reports to the DVCAAR highlighting the monitoring and evaluation of research proposals and proposals, including data analysis.
    i. The IERB membership or change in membership.
    ii. The number of meetings held.
    iii. The number of proposals received and reviewed.
    iv. The number of proposals approved and number returned for minor or major changes

Monitoring of research activities done including protocol deviation or protocol violations and their resolutions, study status evaluations and the recommendations, report of any site visit made, any new information received

    v. That is pertinent to human study participant, plant and animal involvement and how it has been handled.
    vi. To conduct an evaluation of the performance and the services provided by the IERB office staff, including recommendations for process improvement.

THE IERB VICE-CHAIR

a. The IERB Vice-Chair serves as Chair of the IERB, at the direction of/ or in the absence of the IERB Chair.
b. To complete IERB tasks as assigned by the IERB Chair.
c. To serve as a member of the IERB.
d. To coordinate routine functions of the IERB Office.
e. To coordinate and conduct AIU and IERB educational activities designed to improve faculty, staff, and student knowledge of sound ethical research practices.
f. To facilitate the induction of a new IERB member and role responsibilities.

THE IERB MEMBER

The responsibilities of an IERB member shall be:

a. To develop an understanding of ethical principles of research set forth in these IERB SOPs, AIU's research policies, national and international guidelines.
b. To evaluate all proposed and continuing research involving humans, animals and plants submitted to the IERB.
c. To ensure that all approved studies comply with the terms and conditions of approval for the duration of the research.
d. To review IERB proposals, documents and materials assigned to the member prior to the IERB meeting.
e. To attend scheduled meetings prepared to discuss proposals and items on the agenda.
f. To identify and facilitate the resolution of any issues for a given proposal when appointed as a designated reviewer.

g. To participate in and conduct education and training activities in research ethics internal and external to AIU.

THE IERB OFFICE

a. The IERB Office staff shall be composed of at least one (1) Research Officer and one (1) IERB Administrative Assistant.
b. The IERB office shall be located in AIU campus.
c. All staff of the IERB Office shall be employees of AIU.

FUNCTIONS OF THE IERB OFFICE

a. To provide administrative support to the IERB Chair and Vice-Chair.
b. To serve as an interface (with the guidance of the IERB Chair and Vice-Chair) for the investigators, regulatory authorities and any other stakeholders on AIU's IERB matters.
c. To oversee the accurate and timely processing, tracking and filing of all proposals.
d. To effectively communicate with investigators, IERB members, and other interested groups in a timely manner.
e. To maintain accurate records of the IERB activities.
f. To record minutes of meetings.
g. To document communication with investigators and others involved in the conduct of research.
h. To maintain an accurate and comprehensive database of reviewed and approved research.
i. To maintain accurate archiving system that allows for access to open and closed studies.
j. To receive and disseminate any new information, regulation or changes affecting the IERB function or protection of research participants.

IERB MEMBERSHIP

a. The composition of the IERB shall be in compliance with the requirement noted in the NACOSTI accreditation guidelines.
b. The IERB members shall be recommended by the DVCAAR.
c. The IERB shall be composed of at least nine (9) members and a maximum of twenty-one (21) members with varying expertise and possessing the professional competence necessary to promote comprehensive ethical review of research initiatives at AIU.
d. At least one third of the IERB members shall be of either gender.

e. The membership shall include representation from AIU academic schools, as well as external reviewers who have topic expertise, and a lay person from the community, in particular:
    i. At least one (1) Legal expert (i.e. Criminal Justice Representative)
    ii. At least one (1) Community Representative/ lay person
    iii. At least one (1) ISAR Office Representative
    iv. Additional members will be appointed to meet capacity needs as well as other topic expertise requirements.
f. The IERB Chair may invite a subject matter expert to attend a specific IERB review meeting. The invited expert shall assist in the review of complex issues which require expertise beyond or in addition to that available on the IERB. The invited expert is not included in the quorum count to conduct the IERB meeting. The invited expert is expected to participate in the final decision making process.

TERMS OF IERB MEMBERSHIP

a. Members shall be willing to make public their full names, profession, and institutional affiliation.
b. Members shall be expected to report any potential or actual conflicts of interest to the IERB Chair. The IERB Chair will consult the DVCAAR to determine the appropriate action.
c. IERB members and IERB office staff will sign a confidentiality agreement at the beginning of their appointment regarding non-disclosure of deliberations of IERB review activities (**Appendix G**)
d. Each member shall serve for a period of four (4) years. The tenure may be renewed for up to two additional terms, upon approval of DVCAAR.
e. The Deputy Vice Chancellor of Academic Affairs (DVCAAR) in consultation with the Board of Management shall have authority to remove or replace an IERB member.
f. The Deputy Vice Chancellor of Academic Affairs (DVCAAR may terminate the services of or disqualify a member or the IERB on grounds of:
    i. Misconduct.
    ii. Abuse of office.
    iii. Non-disclosure of competing interests.
    iv. Inappropriate behavior.
    v. Unprofessional conduct.
    vi. Failure to abide by the terms of appointment.
g. A member may resign from the IERB on his/her own volition. The member shall be required to submit his/her resignation in writing at least one (1) month notice to allow time to fill the vacancy that will exist as a result of his/her resignation.

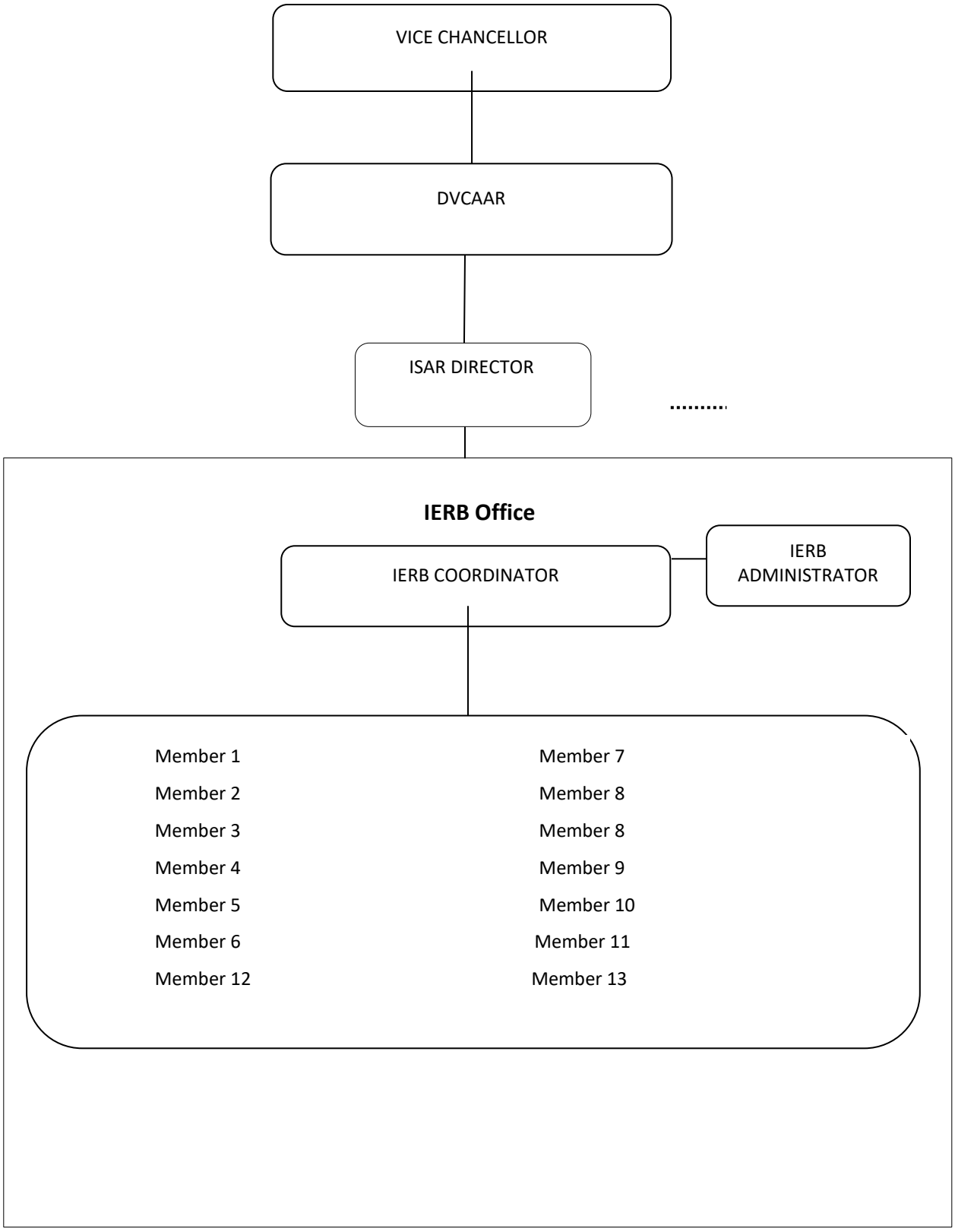
h. When a new member has been appointed to the IERB, an appointment letter from the DVCAAR shall be sent to the new member. The IERB Vice-Chair shall then arrange an orientation session with the new member before they commence their duties.
i. IERB members will be given an allowance for attending IERB meetings and in addition will be reimbursed for any expenses incurred while discharging their duties. The allowances and reimbursements shall be approved by the DVCAAR.

CONTINUING EDUCATION FOR IERB MEMBERS

a. All IERB members shall be required to undertake ethics training.
b. Each IERB member shall be given an equal opportunity to attend bioethics and scientific conferences, workshops or seminars.

IERB Organizational Chart. Found on page x, the organizational chart outlines the organization of the AIU Institutional Ethical Review Board including Management Council, the DVCAAR, and the structure of the IERB office.

IERB Organizational Chart



SOP 2: SUBMISSION OF THE PROPOSAL AND THE IERB REVIEW-

PROPOSAL SUBMISSION REQUIREMENTS

a. The proposal for IERB review of a research study shall be made by the Principal Investigator (PI) for that study. Only one proposal for IERB review shall be submitted for each research study.
b. The PI shall complete the IERB Proposal Submission Form (**Appendix A**), and include it when submitting (4) hard copies of the proposal to the IERB Office. At the same time, the PI shall email a soft copy of the proposal to the IERB office at www.IERB@AIU.ac.ke
c. Proposals will be accepted on Mondays of each week (except Holidays) in the AIU IERB Office for scheduling of the IERB review. The IERB office will forward the proposal to the IERB Chair within 2 business days of receipt. All proposals must be submitted during AIU IERB Office hours.
d. All the relevant documents listed in the IERB Proposal Submission Form must be included in the submission: Informed Consent (**Appendix D**), Informed Assent (**Appendix E**) if applicable, Debrief (**Appendix F**), and PI Confidentiality Agreement (**Appendix G-i**).
e. In the event the PI requests an expedited review, the IERB Office shall refer the request to the IERB Chair for approval (or decline) of the request and scheduling.
f. Incomplete documents shall be returned to the PI.
g. The IERB Office shall receive and log in the proposal and update the IERB Proposal Submission form reflecting a stamped receipt and provide a tentative IERB review date.
h. The IERB Office shall run a plagiarism check on the soft copy of the proposal, and attach outcome report to the proposal before forwarding to the Chair.
i. The Chair will assign and notify three (3) primary reviewers within a maximum of 3 business days from the date the Chair received the proposal.
j. The IERB office shall deliver a soft and hard copy of the proposals to the three reviewers within one business day from the Chair's notification to the IERB office.
k. The primary reviewers shall review the proposals within a maximum of 10 business days, in preparation for the scheduled IERB meeting.
l. The average turnaround time from date of receipt of the proposal in the IERB office to scheduling of the IERB review meeting and outcome of the review is estimated at 30 days.

IERB SCIENTIFIC AND ETHICAL REVIEW

The IERB shall make a scientific evaluation of all research proposals, in particular:

a. The research problem, background analysis, question(s) and/or hypothesis.
b. The study objectives
c. The innovative nature of the proposed research
d. The relevant literature.
e. The research design and methodology (inclusion/exclusion criteria, study procedures, statistical methods, study population, sampling and analytical plan for assessing results).
f. The appropriateness of the budget.
g. The roles and responsibilities of all investigators on the study.
h. The research expertise of investigators on the study.
i. The plans for capacity building and/or technology transfer in the course of the research.
j. The agreements on intellectual property issues prior to commencement of the study.
k. Compliance with relevant style of writing and references.

ETHICAL REQUIREMENTS OF THE REVIEW

The ethical requirements of human research shall include a review of the following:

a. Participant recruitment:
    i. Method of identification of the potential study participants, inclusion and exclusion criteria.
    ii. Method of contacting potential study participants: Contact by the PI through person-to-person contact, letters, flyers and media scripts or through direct advertisement.
    iii. Inclusion of the informed consent form for participant signature
    iv. Screening procedures including administration of a test of understanding and interviews.
    v. Any provisions for compensation of research participants e.g. for their time, transport costs or lost wages. Inappropriate incentives or inducement for participation in the research study.
    vi. Special issues related to research conducted.
    vii. If any deception (e.g. placebos) is included in the methodology, the PI will be required to explain why this is necessary and how ethical concerns will be addressed.
    viii. A copy of the participant debrief form must be submitted with the proposal.
b. The potential benefit to participants, community or society.
c. The relevance of the proposed study to the needs of the community under study

d. The PI's risk assessment for potential harm to participants, i.e. low, moderate, or high risk, and how the risk will be minimized or managed.

e. The safeguards that are included to protect the rights and welfare of vulnerable research participants

f. The adequacy of the methodology to protect confidentiality of the participant and the data.

g. A letter from the research site reflecting approval for the research study, including adequacy of the research site to accommodate provisions for participant confidentiality.

h. In the case of a medical study involving human participants, the research site must have procedures for receipt, custody, control and dispensing of the investigational drugs or medical devices.

i. In the case of a psychological study involving human participants, the PI must have agreement from the research site to provide facilities for confidentiality and to coordinate participant selection and ethical concerns.

j. The adequacy of the informed consent, for the purpose of obtaining informed, voluntary, non–coercive consent or assent.

k. The plans for collection, storage and protection of research data.

l. The plans for dissemination or publication of results – favorable or unfavorable – while maintaining the privacy and protecting confidentiality of the study participants.

m. All significant previous decisions (e.g. those leading to a deferral or modified protocol) by other research regulatory authorities for the proposed study (whether in Kenya or elsewhere) and the indication of the modification(s) to the protocol made on that account. The reasons for the deferral should also be provided.

n. The methodology reflects a data safety and monitoring plan, including the following:

o. Assuring compliance with requirements for reporting adverse events;

p. Monitoring progress of the research process and safety of research participants;

q. Assuring that any action resulting in temporary or permanent suspension of a trial or study is reported to the IERB and relevant authorities;

r. Assuring data accuracy and protocol compliance;

s. Assuring communication and exchange of information among multi-center sites to adequately protect study participants.

SOP 3: IERB DECISION MAKING

The IERB will make one of the following decisions at the IERB review meeting:

3.1 APPROVE THE PROPOSAL

3.2 RESUBMIT WITH CORRECTIONS

3.3 DEFER DECISION

APPROVE THE PROPOSAL

The IERB primary reviewers will complete the IERB Review Form (**Appendix C**) prior to the scheduled IERB review meeting where the proposal decision will be discussed and determined among IERB members. The IERB Proposal Submission Form part D will reflect the approval decision by the IERB.

When the following criteria have been met, the proposal may be approved.

a. The risks to research participants are reasonable in relation to the anticipated benefits
b. The knowledge that is expected to result from the research of public health or clinical importance and/or of advancement of the field of research
c. The risks to research participants are minimized
d. The selection of research participants is equitable
e. Informed consent/assent will be sought from each prospective research participants or their legally authorized representative and will be adequately documented, unless a waiver has been granted
f. The research plan provides for monitoring of data collected
g. There are adequate provisions to protect the privacy of research participants and to maintain confidentiality of the research data.
h. There are adequate safeguards to protect the rights and welfare of research participants.
i. Ethical requirements have been met.
j. Format and content of the research proposal meets acceptable standards of practice, e.g. APA Style, layout, format and content for the full proposal and appendices.

RESUBMISSION OF THE PROPOSAL WITH CORRECTIONS

3.1.1 When Scientific and Ethical Review requirements are not met as listed in SOP 2, a correction shall be required for resubmission. The IERB Proposal Submission Form part D will specify the required corrections and be delivered to the PI by the IERB Office.

3.1.2 Once the corrections are completed, the PI shall re-submit the IERB Proposal Resubmission form (**Appendix B**) to the IERB Office. The PI shall request a resubmission IERB review date and submit the modified study documents highlighting the corrections, along with any additional documents. The IERB Office will schedule the IERB review as outlined in SOP 2.

3.2.3 Corrections are defined as any change to the research proposal, such as:

a. Format and Content: The Proposal does not meet standards of practice due to inadequacies.
b. Ethical issues: The Proposal presents risks to participants, which are not adequately addressed.
c. Recruitment – number of study participants recruitment methods, recruitment materials, selection of study participants etc.
d. Research personnel – PI, Co-PI, students or research coordinators or other investigators on the study.
e. Research sponsor or funding agency.
f. Study site(s) and site letter of consent for research.
g. Study design including but not limited to study population, methodology, study procedures, sample size, equipment, intervention or follow-up procedures.
h. Privacy of information or confidentiality of research participants.
i. Data collection, storage, custody or destruction procedures. This includes revisions to approved questionnaires/surveys or development of a new questionnaire/study instrument.
j. Informed consent/asset-forms, procedures, new or additional information.
k. Debrief process and form.
l. Terms of compensation.

DEFER THE DECISION

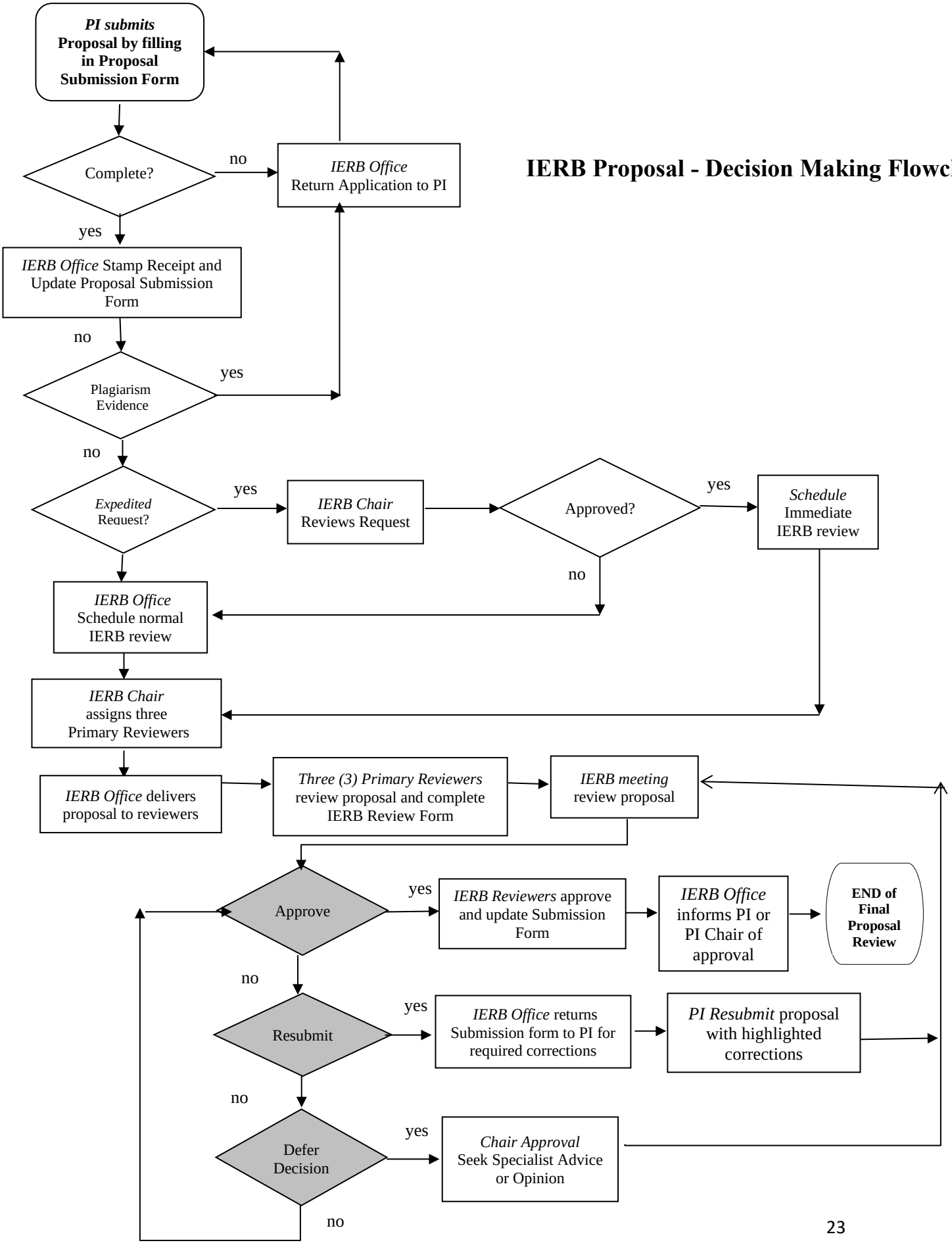
A decision on the research proposal may be deferred until reasons for the deferment have been resolved (**Appendix A, part D**).

a. Defer making a decision until specialist advice or opinion has been sought and received where applicable
b. Request for a re submission of the research proposal if revisions are required.
c. The IERB may appoint an *ad-hoc* subcommittee of three persons to undertake further review of a deferred proposal prior to communicating to the PI. The members of the independent subcommittee shall include at least 2 experts in the field of research pertinent to the proposal. The ad-hoc sub-committee shall be provided with all documents pertaining to the particular proposal that had been reviewed by the IERB. The report from the sub-committee is referred back to the IERB to be utilized for the IERB's final decision on the proposed research study.
d. The IERB Chair may elect to defer the decision at their discretion.

3.2 The IERB Chair shall make the final decision (as outlined in 3.1, 3.2, or 3.3) in the event that the primary reviewers cannot reach consensus on the proposal.

3.3 Any research proposal under the IERB review shall remain on the agenda for no more than ninety days, e.g. decisions are made under provisions 3.2 or 3.3, which require resubmission to the IERB for approval.

3.4 IERB proposal and deferment flowchart (see page x) reflects the process from a submitted research proposal to the IERB review process and decision.


IERB Proposal - Decision Making Flowchart
PI submits Proposal by filling in Proposal Submission Form
Complete?
no
IERB Office Return Application to PI
yes
IERB Office Stamp Receipt and Update Proposal Submission Form
no
Plagiarism Evidence
yes
no
Expedited Request?
yes
IERB Chair Reviews Request
Approved?
yes
Schedule Immediate IERB review
no
IERB Office Schedule normal IERB review
IERB Chair assigns three Primary Reviewers
IERB Office delivers proposal to reviewers
Three (3) Primary Reviewers review proposal and complete IERB Review Form
IERB meeting review proposal
Approve
yes
IERB Reviewers approve and update Submission Form
IERB Office informs PI or PI Chair of approval
END of Final Proposal Review
no
Resubmit
yes
IERB Office returns Submission form to PI for required corrections
PI Resubmit proposal with highlighted corrections
no
Defer Decision
yes
Chair Approval Seek Specialist Advice or Opinion
no

SOP 4: AGENDA PREPARATION FOR THE IERB MEETING-The IERB Office shall prepare the agenda for each IERB meeting to be scheduled on the first Wednesday of each month.

4.2 All completed Proposals received will be scheduled for review by the IERB Chair. In the Chair's absence, the Deputy Chair or other designated member will schedule the IERB review agenda.

4.3 The IERB Chair shall designate three primary reviewers for each proposal under IERB consideration. The primary reviewers must not have either a vested interest in the study (i.e. be named as an investigator or have a supervisory or advisory role) or a conflict of interest (i.e. be involved in the research or in research that competes with the research proposal or proposal under review or have a financial interest in the sponsor or the outcome of the research).

4.5. The format for the IERB meeting may include:

a. Attendance/Apologies
b. Declaration of Conflict of Interest
c. Confirmation of minutes of the previous meeting.
d. Matters arising from the previous minutes.
e. Review and decision of new proposal or proposals.
f. Review and decision of amended protocols.
g. Review of study status reports.
h. Review of final study reports.
i. Review of safety reports.
j. Protocol Deviation / Protocol Violation notifications.
k. Expedited review reports.
l. Any other business
m. Date of the next IERB meeting.

4.5 The agenda shall be prepared showing the proposal unique identification number and its status (e.g. new, amended, study renewal), the title of the study, the name of the PI and the name of the IERB members assigned as primary reviewers.

4.6 The IERB Office will complete and circulate the agenda and any related documents by email at least three (3) working days prior to the IERB meeting dates, which are to be held on the first Wednesday of the month. The agenda will highlight IERB member responsibilities for participation in the IERB meeting.

4.7 The IERB Office will prepare and circulate any documents needed during the IERB meeting.

4.8 Each IERB primary reviewer shall receive one hard copy of the proposal, a soft copy of the proposal by email, and any additional materials submitted with the proposal that the reviewer is assigned to review. In addition, each primary reviewer shall receive an IERB Member Review form (**Appendix C**) to annotate preliminary review of the proposal.

4.4.1 SOP 5: MEETING REQUIREMENTS

5.1. Internal AIU student research proposals:

- Master's Thesis and Doctoral Dissertations must be reviewed by the IERB primary reviewers, in accordance with the AIU SOPs. Students and their thesis supervisor, or dissertation committee chair, will be invited to attend part of the meeting to discuss the outcome decision of the review.

5.2 Internal AIU faculty and staff research proposals:

- AIU faculty and staff proposals shall be reviewed by the IERB primary reviewers, in accordance with the AIU SOPs.

5.3 External (to AIU) applications and research proposals must be reviewed by the IERB primary reviewers, in accordance with the AIU SOPs.

5.4 The IERB shall meet twice a month on the first Wednesday of each month.

5.5 The IERB Chairperson shall convene, unique, special and urgent *ad hoc* meetings, within three (3) to five (5) working days' notice to provide expeditious review of research proposals.

5.6 The IERB primary reviewers shall receive a soft and hard copy of the proposal at least ten (10) days prior to the IERB review meeting. Other IERB meeting attendees shall receive a soft copy of the proposal along with the meeting agenda at least three (3) business days before the meeting.

5.7 The minutes of each meeting shall be documented by a member appointed by the Chair, They shall be reviewed and approved at the next IERB meeting, signed by the chair, and distributed to all members by the IERB office.

5.8 The IERB Chair may invite independent consultants to an IERB meeting or may request them to provide written comments upon review of a proposal. The consultant will sign a confidentiality agreement.

5.9 All the IERB meetings shall be chaired by the Chairperson; if the Chairperson is not available, the Deputy Chairperson will conduct the meeting. If the Deputy Chairperson is not available, an alternate will be elected from the members present among themselves. This arrangement shall be recorded in the minutes of the meeting.

5.10 All assigned primary IERB reviewers must be present at their scheduled review meeting to evaluate and determine the outcome of the review.

5.11 The three (3) primary IERB reviewers assigned to review a proposal must attend the review meeting.

5.12 The 3 members designated as primary reviewers will initiate discussions on the research proposal, identify any scientific or ethical issues and facilitate the resolutions of any issues on the proposal.

5.13 A quorum shall constituting at least five (5) IERB members, including the three primary reviewers, must occur otherwise the IERB meeting shall not be held or proceed.

5.14 If quorum is not sustained during a meeting, the IERB shall not make a decision on a research proposal until the quorum is restored. If quorum cannot be restored, the meeting shall be stopped and re-scheduled.

5.15 An IERB reviewer shall not miss more than 3 or 25% of assigned meetings per calendar year, this means the IERB reviewer must participate in 75% of assigned IERB review meetings. A member who fails to attend the required minimum will be required to give a written explanation to the DVCAAR for his action.

5.16 Attendance of a Principal Investigator

a. The IERB Chairperson or IERB office shall invite a PI, in writing, to attend the meeting at which his/her proposal requires further clarification or discussion. The PI shall not be required to make any formal presentation of the study at the meeting, unless requested to do so.

SOP 6: MINUTES OF MEETINGS: REV. ENOCH OPUKA

6.1 The IERB Office shall be responsible for preparing and maintaining detailed minutes of each IERB meeting.

6.2 The minutes of the meetings shall include the following items:

a. Attendance, including members present, absent and apologies received.
b. Quorum shall be documented (number and composition).
c. Any conflict of interest related to each protocol reviewed during the meeting.
d. The names of IERB members who abstained from participating in the deliberations and in taking a vote on a specific research proposal or proposal due to competing interests.
e. The time the meeting was started and closed.
f. The approval of previous meeting minutes.
g. The resolution of action items from the previous meeting.
h. The AIU number assigned to the proposal or the assigned non AIU number, the PI, the type of review, the title of the proposal and the time frame within which the research will be completed.
i. The level of risk the proposed study presents to research participants and appropriate related protective actions for human (or animal) participants.
j. The discussion and decision taken by the IERB.
k. A detailed summary of the ethical issues identified and discussed in relation to a new research proposal, an amended protocol, annual or status reports, incident and adverse event reports and any other items on the agenda.
l. A summary of the discussion of dissenting issues and their resolution or required action. All dissenting opinions will be noted in the minutes but no particular view will be attributed to a particular IERB member.
m. The basis for requiring modification in or for disapproving research.

n. The number of IERB members voting for, against, abstaining or absent from the IERB's action on each proposal whenever a vote is taken.
o. The approval period for completion of the research.
p. The name of the PI who attended the meeting (or had been invited to attend) for discussion on their research proposal.
q. The date and signature of the Chairperson.

6.3 The minutes shall be produced and emailed to all IERB members within five (5) working days following the relevant meeting.

6.4 The IERB members shall be given an opportunity to seek clarifications, request for changes or corrections to the minutes prior to adoption at the next convened IERB meeting.

SOP 7: THE INFORMED CONSENT AND INFORMED ASSENT PROCESS:

Informed consent and informed assent are continuous processes that start with the researcher's first contact with the perspective participant. The written Informed Consent and Informed Assent forms shall provide adequate information to enable the potential participant to make an informed choice about his/her participation. The ethical standards required in obtaining informed consent shall apply to informed assent.

7.1 Requirements of Informed Consent

a. The IERB shall require the PI to obtain a signed informed consent form (**Appendix D**) from each prospective study participant. Consent shall be required from adults aged 18 years and .
b. The Consent form needs to provide comprehensive (without technical terms) written and verbal information to be given to the research participant, or their legally authorized representative.
c. Individuals, who cannot consent to participate in the research due to disability or inability, shall require a legally authorized representative to provide consent.
d. For non-English speaking potential participants, the Consent form shall be translated in writing, into Kiswahili or other relevant languages. A translator must accompany the PI to verbally communicate and ensure understanding of the consent form before the participant signs. The translator must sign a confidentiality form (**Appendix G-ii**).

7.2 Requirements of Informed Assent

a. Instructions for child participation in research, i.e., aged 18 years and below, are outlined in Appendix E-i and E-ii.

b. A Parental Informed Consent form is required to be signed by the parent or legal guardian, granting permission for the child's participation in research (**Appendix E-iii**). In addition, the child shall sign an Informed Assent form to agree to participate in the research (**Appendix E-iv**).
c. For non-English speaking potential participants, the Assent form shall be translated in writing, into Kiswahili or other relevant languages. A translator must accompany the PI to verbally communicate and ensure understanding of the Assent form before the participant signs. The translator must sign a confidentiality form (**Appendix G-ii**).
d. For children who are unable to provide assent due to developmental age or a condition, parental consent will be considered as sufficient, upon review by the IERB.

7.3 The table below should be used as a guide in deciding if participation in research is possible for children aged 17 and younger:

If Parent Consents to Participate (YES/NO)	If Child 17 or below Assents to participate (YES/NO)	Can the research include the Child who is 17 or below?
YES	YES	YES
YES	NO	NO
NO	NO	NO
O	YES	NO

Table 1 Source: Modified from KEMRI SOPs 2009

7.4 Obtaining Informed Consent from a Married Minor

a. The IERB shall consider a mature minor (i.e. emancipated minor, independent, and no longer dependent on parents) as any individual less than (18) years of age that is married.
b. The potential participant who is a mature minor must sign the Informed Consent form as indicated in section 7.1 above.

7.5 Community Considerations

During the evaluation of a research proposal, the IERB shall consider the following issues:

a. The steps taken to consult with the concerned communities during the course of conducting the research and in disseminating research findings are transparent

b. The proposed community engagement process including public barazas, permission from the community elder or persons acknowledged as community representatives and where applicable, the establishment of a Community Advisory Board (CAB).
c. The manner in which the results of the research will be made available to the research participants and the concerned communities.
d. The consideration for cultural sensitivities and concerns.

7.6 Obtaining Consent from Vulnerable Populations

a. The IERB shall require that that exceptional consideration is given to protecting the welfare of the particularly vulnerable groups, e.g. such as children, pregnant women, neonates, fetuses, homeless youth, cognitively impaired persons, internally displaced persons, economically or educationally disadvantaged persons, marginalized social groups, or individuals with terminal illnesses or prisoners.

b. In its assessment of research involving vulnerable groups, the IERB shall require that:
    i. The objective of the proposed research is to obtain knowledge relevant to the needs of the population under study
    ii. The PI demonstrates that the research question cannot be answered if the study is carried out among a less vulnerable group
    iii. The study participants are explicitly told that they are taking part in the research, requiring standard informed consent procedures.
c. The requirements for obtaining and documenting consent/assent documents are tailored to the needs of the individual from the chosen vulnerable group i.e. use of appropriate language, content of the consent/assent documents and the explanation of the procedures to be followed.

7.7 Documentation of Consent

a. The IERB shall require that informed consent be documented by use of written approved consent form.
b. The consent form must be signed and dated by the research participants or legally authorized representative at the time of consent.
c. A copy of the signed and dated consent form should be given to the person(s) signing the consent form, the original consent form shall be assigned a number, and stored in an appropriate manner to protect the participants' confidentiality.

SOP 8: REVIEW OF ANNUAL REPORTS:

8.1 An annual report, based on the prior calendar year, shall be completed by IERB Office and submitted to the IERB Chair no later than March 1st each year. The IERB Chair shall review the report with the IERB members for discussion and final approval at a scheduled IERB meeting.

8.2 The annual report shall be submitted to the IERB accreditation body no later than May 1st each year, by the IERB Chair.

8.3 The annual report shall cover the period from January 1st to December 31st of the prior calendar year.

8.4 The report should include the following:

a. The total number and list of all proposals reviewed during the year by the IERB (**Appendix H**), to include:
    i. The number of approved proposals at first submission
    ii. The number of resubmitted proposals (after corrections), which were approved
    iii. The number of deferred proposals (after re-review), which were approved.
b. A list of all approved proposals is to be prepared to include:
    i. The Research title
    ii. Principal investigators and co-investigators and their qualifications
    iii. The institution where the research was conducted.
    iv. The date of IERB approval for the proposal.
c. The total number of IERB meetings held during the year, according to the IERB calendar.
d. The IERB member participation
    i. List of names of IERB members and the number of meetings attended for each member.
    ii. List of names of IERB members who were appointed as primary reviewers
        a. The number of proposals reviewed for each primary review
    iii. List changes in appointments in IERB membership
        a. The names and number of any members who completed their term.
        b. The names and number of any members who resigned.
        c. The names and number of any members who retired from AIU.
        d. The names and number of any members who were dismissed.
        e. The names and number of any new member appointments.
e. A description of the training activities that were conducted, specifically:
    i. The number of trainings
        a. The number of IERB member certification trainings conducted
        b. The number of new IERB members who were certified.
    ii. The types and titles of other trainings.
    iii. The IERB members or other facilitators who conducted the trainings
    iv. The names of the IERB members who attended the trainings

f. Bi-annual report of the status of internal AIU monitoring or evaluation will be submitted to senate through the deans committee including:
    i. Report to be completed by the IERB office by May 1st and internally to the Quality Assurance department by December 1st of each year
    ii. List of PI names and research titles that were monitored.
    iii. Status of progress reports submitted by the PI.
g. A description of any changes in the IERB SOPs or guidelines for operation.
h. A summary report of IERB activity for the year
    i. Summary of number of external and internal proposals approved.
    ii. Summary of accomplishments, challenges and changes
    iii. Summary of recommendations and plans for improvement of IERB operations.

SOP 9: REVIEW OF STUDIES INVOLVING ANIMALS AND PLANTS:

1 This IERB is designated by AIU to approve the initiation of, and performance of, periodic review of all research conducted. This includes studies involving animal subjects and plant subjects.

9.2 The IERB shall follow the procedures outlined in SOP 2 regarding submission of IERB proposals.

9.3 Any proposal for research involving animals or plants must include:
a. The study protocol and any supporting documents.
b. Studies involving animals: An approval letter from an accredited Animal Care Use Committee (for example: KEMRI's ACUC), must be included in the proposal.
c. Studies involving plants: An approval letter from an accredited Plant Resource Use Committee (PRUC) must be included in the proposal.
d. CV's of veterinary experts, animal care staff and of all non-AIU affiliated investigators on the study.
e. The specialized experts are required to attend the IERB review meeting (SOP 1)

9.4 The IERB review shall make an assessment including the following:
a. The justification for the use of animals and plants.
b. The arguments in support of the chosen animal species or model.
c. The training and expertise of veterinarians and animal care staff on the study.
d. The biosafety measures instituted in all aspects of the study.
e. The potential benefits and harms presented by the study and the possibility of reducing the harms.

9.5 Refer to SOP 3 regarding IERB Decision Making

9.6 The IERB shall conduct an interim review of the animal and plant studies to re-evaluate the actual risk benefit status of the study, identify possible areas of improvement for optimal implementation of the study, and any needs for further training or expert advice.

SOP 10: FEE FOR REVIEW:

10.1 Internal AIU proposal reviews: At the time of writing, the IERB does not require any fees for initial review of research proposals. However, if the PI is required to resubmit the proposal for corrections for a third (or more) review by the IERB, a fee may be assessed to the PI.

10.2 External to AIU proposal reviews: A policy on IERB review fees at AIU, for external proposals may be introduced at any time by the DVCAAR and the VC.

10.4 How much money students/ supervisor should pay for their work to be reviewed by IERB

10.3 issue of sitting allowance for reviewers.

SOP 11: PROCESS FOR ADVERSE EVENTS:

11.1 The IERB shall require the PI to immediately report any adverse events during the conduct of a study.

11.2 The IERB shall consider an adverse event as any unfavorable and unintended sign or abnormal symptom or finding that was not foreseen in the risk assessment or methodology section of the previously IERB approved proposal. This includes an abnormal finding of an investigational treatment or procedure regardless of whether or not it has a causal relationship.

11.3 The PI must suspend the study including any further data collection activities until the IERB Chair has revoked the suspension.

11.4 Any study-related unexpected or serious adverse event must be reported to the IERB Office by telephone immediately, followed by email within twenty four (24) hours after the PI becomes aware of the event.

11.5 The PI shall write a report stating the date and time the study was suspended. The PI report shall describe the adverse event, its impact, recommended remedy. The PI report shall also request an IERB review date.

11.6 The IERB Office will contact the IERB Chair to convey the PI's report of the suspended study and the adverse event. The IERB Chair will schedule an expedited IERB review meeting within 7 days , where the next course of action will be decided. The IERB Chair will inform the three (3) primary reviewers who approved the study to attend the expedited review meeting.

11.7 The IERB shall communicate to the PI, in writing, its decision or its intention to take a particular action within five (5) working days of the date at which the decision was made at the IERB review meeting.

SOP 12: PROTOCOL DEVIATIONS OR PROTOCOL VIOLATIONS

12.1 The IERB shall consider a protocol deviation or violation as any failure to adhere to the defined procedures or treatment plans outlined in the proposal version previously approved by the IERB.

12.2 The IERB shall consider a protocol deviation or violation as any planned or inadvertent changes that may or may not impact safety of study participants; for example: deviations or violations that affect the integrity of study data and/or affect study participants' willingness to participate in the study previously approved by the IERB.

12.3 IERB shall require the PI to immediately contact the IERB office by email or phone to report any deviation or violation. All email communication should be encrypted for safety. The PI must submit a deviation/violation report to the IERB office within five (5) business days following the email or phone report.

12.4 The IERB Office will contact the IERB Chair to convey the PI's report of the protocol deviation or violation.

12.5 The IERB Chair will schedule an expedited IERB review meeting. The IERB Chair will inform and invite the three (3) primary reviewers, who approved the original study, to attend the expedited review meeting.

12.6 The IERB review shall assess the deviation or violation report (Appendix), and determine the appropriate course of action.

12.6 The decision of the IERB review, including any instructions, will be communicated by the IERB Office to the PI within five (5) business days of the IERB review meeting at which the decision was reached.

SOP 13: FINAL RESEARCH PRODUCT: IERB REVIEW AND REPORT:

13.1 Internal (to AIU) research studies conducted by AIU students:

a. They shall be monitored by the Master's student's thesis supervisor or Doctoral dissertation Chair.

b. Once the IERB has approved the proposal, the monitoring responsibility for conducting the study is that of the thesis supervisor or doctoral chairperson assigned to the student.

c. The IERB Office shall receive the final research product from the thesis or dissertation student at least one month prior to the student's supervisor or chair approval signatures, in order for the IERB to complete its final research review report.

d. The IERB Office will prepare a final review report, providing comments of a satisfactory completion or unsatisfactory completion. Unsatisfactory research products would include non-compliance with the IERB approved research proposal.

e. The IERB final research product review report will be sent to the thesis supervisor or doctoral chair for review and determination before signing off on the student's final research thesis/dissertation.

f. The student will submit hard copies and electronic copies of the final research product to their thesis supervisor or Dissertation Chair for signatures of approval.

g. The Dean's office will submit the final research product to the AIU library to be published in the AIU research depository.

13.2 Internal (to AIU) research studies completed by AIU faculty or staff:

a. The faculty and staff shall submit their final research product to the IERB Office.

b. A monitoring and evaluation report will be prepared by the Research office (M & E desk) and submitted to the IERB Office.

c. The IERB Office will prepare a final review report, providing comments of satisfactory completion or unsatisfactory completion. Unsatisfactory final research product would include non-compliance with the IERB approved research proposal.

d. The final review report will be sent to the faculty member and the respective Dean's office; or the final review report will be sent to the staff member and the respective supervisor for review and determination.

e. The IERB Office encourages the faculty and staff to work with the research office to publish the final research product.

13.3 External (to AIU) research studies

a. The external research PI shall follow the IERB approved proposal without deviation.

b. The external research PI shall submit their final research product to the IERB Office.

c. A monitoring and evaluation report will be prepared by the ISAR (M & E desk) and submitted to the IERB Office.

d. The IERB Office will prepare a final review report, providing comments of satisfactory completion or unsatisfactory completion. Unsatisfactory final research product would include non-compliance with the IERB approved research proposal.

e. The final review report will be sent to the ISAR Office, the PI, and the research sponsor as the case maybe

SOP 14: IERB SUSPENSION OR TERMINATION OF ETHICAL APPROVAL:

14.1 Internal Proposals:

a. The IERB shall have the authority to suspend or terminate ethical approval for Student, Faculty or Staff research where it is the IERB's findings that the research is not being, or can no longer be, conducted in accord with provisions of the approved protocol.

b. The IERB Chair shall appoint a minimum of three (3) IERB members to review the specific ethical concerns and summarize its recommended actions. The IERB Chair may elect to review the case at the next IERB review meeting, for IERB member input and recommendations.

c. The IERB Chair in coordination with the DVCAAR will determine the remedial actions that shall be required by the PI, which may include but are not limited to:

i. Suspension of the all research activity until:

a. Ethical safeguards are developed by the PI and approved by the IERB Chair.
b. The IERB Chair directs, in writing, the requirements that the PI must meet in order to continue the research. Upon the PI meeting the specified requirements, the research may continue. If the PI does not meet the specified requirements, the research is terminated.
c. The IERB Chair institutes a monitoring plan for the duration of the PI's research activity, by appointing two IERB members to implement the monitoring plan.

ii. Termination of the research activity:

a. The IERB Chair and IERB members may recommend termination of a PI's research when severe ethical issues are identified, and corrective actions are not feasible or appropriate.
b. The IERB Chair, in coordination with DVCAAR shall make the decision to terminate the PI's research activity. The IERB Chair will inform the PI of the administrative decision in writing.

14.2 External Proposals:

The IERB's function for external proposals is limited only to the review and approval of research proposals. Therefore, AIU does not assume responsibility for the actions of the PI or ethical issues that may arise during the research conducted by external PI or their assignees.

SOP 15: COMPLAINTS OF RESEARCH CONDUCT:

15.1 The IERB Office shall be the point of contact for handling complaints regarding the conduct of a research study.

15.2 The name and contact information of the IERB Office shall be included in all informed consent/assent documents for all studies, so that participants in a study have contact information if needed.

15.3 Any individual with a complaint about the conduct of a study will be required to bring the complaint to the attention of the IERB Office, in the form of a written letter. The IERB Office shall notify the IERB Chairperson of the complaint or concern.

15.4 Upon receipt of a complaint or concern, the IERB Chairperson will send a written notice of the allegations to the PI within three (3) business days from the date the complaint was received. The PI shall be required to respond, in writing, to the IERB Chair regarding the complaint within three (3) business days.

15.5 The IERB Chair will appoint at least 3 (three) IERB members to review the complaint and submit a summary of recommendations to the IERB Chair.

15.6 The IERB Chair may schedule a review meeting with IERB members to review the recommendations, or the IERB Chair may schedule an expedited ad-hoc review meeting to discuss the complaint and potential resolutions, if any.

15.7 The IERB members shall review all allegations of serious or continuing non-compliance with IERB requirements at the next scheduled IERB meeting. Non-compliance involves conducting research in a manner that disregards or violates the IERB's regulations and/or a protocol.

15.8 The IERB Chair shall determine to initiate an investigation of the complaint or concern. The investigation will take no longer than ten (10) business days from the date of receipt of the complaint or concern.

15.9 The IERB members will then proceed to review both the allegation and response received from the PI and other relevant information upon which the IERB reviewers may recommend:

a. Dismissal of the allegation or complaint as unjustified.

b. Referral of the matter to another more appropriate process or authority within the respective institutions or other relevant authority for resolution.
c. Resolution through corrective or educational measures where the violation is minor or inadvertent.
d. The launch of a formal IERB investigation where the allegation or complaint appears founded and is of a serious nature.

15.10 The IERB shall maintain confidentiality to protect the identity of person(s) making allegations. In addition, the IERB shall maintain confidentiality with regard to the complaint and related details of the case.

15.11 The IERB Chair will determine, in coordination with the DVCAAR:

a. The appropriate action(s) to be taken to notify, or not notify, the PI or complainant regarding the IERB discussions or decisions on the complaint.

b. The extent of information to be disclosed and rationale for disclosure to the PI or complainant.

c. IERB members involved in any review process shall maintain confidentiality with regard to matters of the specific complaint or related to the complaint.

SOP 16: IERB DECISION APPEALS:

16.1 The PI has the right to appeal an IERB decision. Any appeal shall be filed by the PI.

16.2 The PI may appeal an IERB review decision by submitting a written letter describing the reasons for the appeal. The written appeal is submitted by the PI to the IERB Office. The IERB Office will forward the appeal to the IERB Chair, who will schedule the review at the next IERB meeting.

16.3 The IERB Chair shall review the documents provided by the PI to determine if further investigation is warranted. If it is determined that the appeal deserves further investigation, then an Independent Appeals Committee will be constituted by the IERB Chair in coordination with the DVCAAR Research, and the DVCAAR to undertake review of the petition documents.

16.4 In conducting its review, the appointed Independent Appeals Committee (IAC), which is established by the DVCAAR, shall consider whether the IERB acted in compliance with:

a. IERB Standard Operating Procedures
b. AIU Research and/ or other AIU policies

16.5 The appointed Independent Appeals Committee will notify the IERB Chair, in writing, the outcome of the investigation which may be:

a. Dismissal of the appeal, in which case the decision will be final. The IERB Chair shall notify the PI of the outcome of the IAC decision, in writing, within five (5) business days from the date the decision was reached.

b. Referral back to the IERB for re-consideration with new information obtained by the IAC. If the appeal file is referred back to the IERB for further evaluation, the IERB's decision on the matter shall be final. The IERB Chairperson shall communicate to the PI, in writing, within five (5) business days of the meeting at which a final decision on the matter was reached.

SOP 17: CONFIDENTIALITY AND ETHICAL RESPONSIBILITIES OF IERB MEMBERS:

17.1 All IERB members, including internal and external members, shall adhere to strict ethical responsibilities to maintain confidentiality of records, review discussions and decisions.

17.2 All IERB members (**Appendix G-iii**), IERB visiting members (**Appendix G-iv**) and IERB Office staff (**Appendix v**) shall be required to sign a confidentiality and ethics agreement upon appointment.

17.3 All IERB documents shall be delivered to the respective IERB members' offices by the IERB Office staff. Non-IERB staff shall not handle IERB documents.

17.4 At the end of each IERB meeting, the IERB office will return all members' meeting files to the IERB Office. The IERB office will be responsible to maintain security and confidentiality of research proposals and other documents in a locked cabinet.

17.5 At the end of each IERB meeting, the IERB members will submit their evaluation reports to the IERB Chair who will forward them to the IERB Office. The IERB Office will maintain security and confidentiality of meeting documents in a locked cabinet.

SOP 18: ARCHIVAL OF IERB DOCUMENTS:

18.1 All documentation and communication within the IERB operation shall be dated, filed, and archived. The IERB office shall be responsible for accessing and retrieving of various documents, files and archives in electronic form.

18.2 All approved proposals and related IERB documents shall be retained in an electronic format by the IERB Office.

18.3 The electronic files for approved proposals and related IERB documents will be retained for a minimum of 10 years within the IERB Office. IERB liaise with library and IT to store the electronic documents.

18.4 Any final versions of hard copy documents shall be converted to electronic format for archival purposes by the IERB Office. The IERB Office shall shred the hard copies 90 days after conversion to electronic format.

18.5 The IERB Office shall electronically archive all documents related to the IERB operations, including but not limited to:

a. The AIU approved Standard Operating Procedures for the IERB.
b. A list of current IERB members, including beginning and ending of terms of appointment.
c. The Curriculum Vita of all IERB members
d. The IERB membership summary list including earned degrees; representative capacity, expertise, employment or institutional affiliation of each member.
e. The training and IERB certification records training of all IERB members and IERB office staff.
f. The agenda of the IERB meetings by calendar year
g. The minutes of the IERB meetings by calendar year
h. IERB month-to-date and year-to-date data collection form, i.e. from beginning of IERB operation to current date (**Appendix G**)
i. All approved IERB related forms
j. Approved research proposals and related IERB documents, including correspondence.
k. Records of adverse actions, appeals, complaints and related meetings and outcome reports.
l. Records of monitoring and evaluation reports.
m. Records of communication to the IERB, including to the IERB Office, IERB Chair, and IERB members.
n. The final report of the study.
o. Record of all site and/or audit visit
p. All IERB reports.
q. The electronic database files.

SOP 19: AMENDING THE IERB STANDARD OPERATING PROCEDURES:

19.1 Any IERB member or interested party may submit a recommendation for an amendment to the SOP. The recommendation shall be in writing and delivered to the IERB Office. The IERB Office will forward to the IERB Chair.

a. The IERB Chair will schedule an IERB meeting to review the recommendation with IERB members and to decide the outcome of the recommendation and related next steps.
b. The IERB Chair will reply to the recommending party within 30 (thirty) business days from the date of receipt of the recommendation in the IERB Office.

19.2 Any amendment to the SOP shall be approved by the IERB Chair in coordination with the DVCAAR. If the amendment is approved:

a. The revised SOP will be written by IERB members who are appointed by the IERB Chair. The revised language for the related SOP will be delivered to the IERB Chair.
b. The revised SOP shall be approved by the IERB Chair and DVCAAR.
c. The IERB Chair will provide the IERB Office with the revised SOP and written authorization to make the changes to the IERB SOP document.
d. The IERB Office will update the SOP according to the approved revisions received from the IERB Chair and will provide the IERB Chair with a bounded copy of the updated SOP. The IERB Chair shall sign approval and effective date of the updated SOP and forward the original back to the IERB Office for archival purposes.
e. The IERB Office will circulate an electronic version of the new SOPs to all IERB members and to AIU Administration. The IERB Office shall disseminate the updated SOP via email distributions, web postings or educational sessions.

19.3 Any proposed amendment to an SOP or SOPs that are not adopted by the IERB, shall not be effected.

REFERENCES

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AIU (2010). *Research Handbook*, United States International University-Africa

APPENDICES

APPENDIX A: IERB PROPOSAL SUBMISSION FORM- *(AIU/IERB Form 2017-1)*

Instructions:

1. This submission form should be filled in by the Principal Investigator
2. Only one proposal for IERB review should be made for any research study
3. All the relevant documents listed in this IERB Proposal Submission Form must be submitted
4. Incomplete proposal submissions will not be processed

Part A: Proposal Information to be completed by Principal Investigator

Submission Date: _____ Title of Study:_____

Type of Submission for IERB Review: ☐ **New proposal** ☐ **Resubmission**

Expected Study Start Date:_____Expected Study End Date: _____

Principal Investigators Name	**E-mail Address**	**Telephone Number**
Other Researchers(if any) Names	**E-Mail Address**	**Telephone Number**

Type of Study: Check One

AIU Internal Research	***External Research**
☐ AIU Doctoral Student Research	☐ Organization/Agency Research
☐ AIU Masters' Student Research	☐ Professional/Individual Research
☐ AIU Undergraduate Student Research	☐ Doctoral Student Research
☐ AIU Faculty Research	☐ Masters Student Research
☐ AIU Staff Research	☐ Undergraduate Student Research

***External Research:**

Name of PI Institution:

_____

Name & Contact at PI Institution:

_____

The Participants in the Proposal will include:

☐ Human Subjects ☐ Adults, 18 years and above ☐ Minors, 17 years old and below ☐ Animal Subjects ☐ Plants

APPENDIX A: IERB PROPOSAL SUBMISSION FORM

Part B: Principal Investigator Research Proposal Submission Checklist

Please ensure that the following items are attached when submitting the proposal to the IERB Office:

- ☐ **Research Proposal must include**:

Chapter 1: Introduction. This should cover the background to the problem, statement of the problem, objectives of the study, research questions, purpose of the study, justification for the study, limitation of the study, definition of terms and the chapter summary.

Chapter 2: Literature Review

Chapter 3: Research Methodology. At minimum shall include the research design, site selection, participant selection with inclusion/exclusion criteria, pre-screening of participants, participant consent, description of risk assessment and methods to reduce risk, participant debrief, data collection, instrumentation, method of data analysis/validity/reliability, ethical considerations including methods to ensure participant confidentiality, i.e. stored data, non-disclosure of participant identification, disposal of data at conclusion of research.

References in compliance with APA or other relevant style of writing and referencing

Appendices

- ☐ Principal Investigator(s) Curriculum Vitae
- ☐ Participant Informed Consent, Parent Consent/Child Assent Forms (As Applicable)
- ☐ Debrief Form
- ☐ PI and Other Researchers'(if any) Signed Confidentiality Agreements
- ☐ 4 Hard Copies of all submission documents
- ☐ 1 Soft Copy of all submission documents

Part C: Principal Investigator Declaration

As the Principal Investigator of this study I hereby declare that I take full responsibility for this proposed study and will conduct it according to the documented proposal and in line with AIU IERB ethical guidelines.

By signing this document, I agree that:

a) All documents submitted with this application are a true representation of the proposed study and have not been falsified in any way.
b) This study will not commence in any way, and no participants will be recruited, until a final official approval is received from AIU's IERB.
c) Ethical standards of practice will be maintained during this research. The study will be conducted as stated in the submitted protocol. All participants will be recruited and consented as stated in the submitted protocol.
d) Any planned or any unforeseen protocol deviations or protocol violations -to the submitted study- must be reported to AIU's IERB in writing by email to

joash.mutua@africainternational.edu immediately. The Deviation/Violation Report Form must be submitted to the IERB office within five (5) business days of the email to the IERB Office.

e) Any unexpected or serious adverse event during the research must be reported to the IERB Office by telephone **(0743513617)** immediately, and by email to isar.aiu@aiu.ac.ke within twenty four (24) hours after the PI is aware of the event.

Principal Investigator Signature	**Date**

APPENDIX A: IERB PROPOSAL SUBMISSION FORM

Part D: For IERB Office Official Use

Assigned IERB Proposal Number:	
Received By Name: **Received by Date:**	Official Stamp and Date

Date IERB Review Scheduled:
Assigned Primary IERB Reviewers Reviewer 1: Name _____ Reviewer 2: Name_____ Reviewer 3: Name_____
IERB Review Decision: ☐ Approve the Proposal

☐ Require Resubmission of the full proposal with highlighted corrections by: Date: _____ ☐ Defer Decision Reason for Deferral:
IERB Review Comments

APPENDIX B: IERB PROPOSAL RE-SUBMISSION FORM-*(AIU/IERB Form 2017-2)*

Instructions:

1. This re-submission form should be filled in by the Principal Investigator
2. The proposal re-submission should be submitted within 14 days of the request for re-submission
3. All changes to the original proposal submission should be highlighted in the documents
4. The resubmitted proposal shall show highlighted changes made.
5. All the relevant documents listed in this IERB Proposal Re-Submission Form must be submitted
6. Incomplete proposal re-submissions will not be processed

Part A: Proposal Details

Resubmission Proposal Number: R-_____(Original number preceded by 'R')

Date of Re-Submission: (dd/mm/yyyy): _____This is the first ____ second ____ third ____ resubmission.

Principal Investigators Name	**E-mail Address**	**Telephone Number**
Other Researchers	**E-mail Address**	**Telephone Number**

Title of Study:

_____

Study Start Date: _____ **Proposed End Date:** _____

Part B: Description of Changes

Describe the changes made to the proposal submission with page references

Description of Corrections	**Page Reference**

APPENDIX B: IERB PROPOSAL RE-SUBMISSION FORM

Part C: Submission Checklist

Please ensure that the following items are attached together with this proposal re-submission form for IERB Review. Where changes have been made to previously submitted proposal, they should be clearly highlighted.

- ☐ Research Proposal showing the:
  - Chapter 1: Introduction. This should cover the background to the problem, statement of the problem, objectives of the study, research questions, purpose of the study, justification for the study, limitation of the study, definition of terms and the chapter summary.
  - Chapter 2: Literature Review
  - Chapter 3: Research Methodology. This should include the research design, participant selection with inclusion/exclusion criteria, pre-screening of participants, participant consent, description of risk assessment, participant debrief, data collection, instrumentation, method of data analysis, validity and reliability, ethical considerations.
  - References in compliance with APA or other relevant style of writing and reference
- ☐ Principal Investigator(s) Curriculum Vitae
- ☐ Informed Consent/Assent Form
- ☐ Risk Assessment Form
- ☐ Debrief Form
- ☐ 4 Hard Copies of all submission documents
- ☐ 1 Soft Copy of all submission documents

Part D: Principal Investigator Declaration

As the Principal Investigator of this study I hereby declare that I take full responsibility for this proposed study and will conduct it according to the documented proposal and in line with AIU IERB ethical guidelines.

By signing this document, I agree that:

f) All documents submitted with this application are a true representation of the proposed study and have not been falsified in any way

g) This study will not commence in any way and no participants will be recruited until a final official approval is received from AIU's IERB.

h) The study will be conducted as stated in the submitted protocol. All participants will be recruited and consented as stated in the submitted protocol

i) Any protocol deviations or protocol violations to the submitted study must be reported to AIU's IERB in writing by email to isar.aiu@aiu.ac.ke within five (5) business days of the

deviation or violation using the Sample Protocol Deviation or Protocol Violation Reporting Form

j) Any study-related unexpected or serious adverse event must be reported to the IERB Office by telephone immediately (0743513617), followed by an email to joash.mutua@africainternational.edu within twenty four (24) hours after the PI becomes aware of the event.

Principal Investigator Signature	**Date**

APPENDIX B: IERB PROPOSAL RE-SUBMISSION FORM

Part E: For AIU IERB Official Use

Date IERB Review Scheduled:
Assigned Primary IERB Reviewers Reviewer 1: Name _____ Reviewer 2: Name_____ Reviewer 3: Name_____
IERB Review Decision: ☐ Approve the Resubmitted Proposal ☐ Require Resubmission with full proposal with highlighted corrections by Date: _____ ☐ Defer Decision Reason for Deferral:
IERB Review Comments

APPENDIX C: IERB PROPOSAL REVIEW FORM-*(AIU-/IERB Form 2017-3)*

IERB Proposal Number _____ Principal Investigator Name _____

Instructions: Each IERB primary reviewer shall review the assigned proposal prior to the scheduled IERB review meeting. The following criteria shall be reviewed and the primary reviewer will check yes or no regarding each item below. IERB reviewers shall bring the completed review form and proposal to the scheduled review meeting.

1. The proposal must meet the standard format, which must include the following six (6) sections: Front Matter, Chapter 1, Chapter 2, Chapter 3, References, Appendices
2. Specifically, the following content items shall be reviewed by the IERB reviewers. All items must meet YES response for the proposal to be approved. Primary reviewers will then consult at the review meeting.

Instructions: Check YES or NO for each of the following items in the proposal.	YES	NO
The front matter follows standard format and numbering		
The introduction sections in Chapter 1 are documented and content is written clearly.		
The literature review in Chapter 2 is comprehensive and inclusive for aspects of the specific study.		
The methodology in Chapter 3 includes all required sections and content is written clearly.		
The specific protocol procedures for instrumentation and methodology are clearly explained.		
The data analysis in methodology is clearly explained and understandable.		
The selection of participants is adequately explained, including inclusion and exclusion criteria.		
The Informed consent form(s) are acceptable and are specific to the study, copy in Appendix		
The assent form (participants under 18 years old) is written specific to the study, copy in Appendix		
The parental consent form (if assent form used) is written specific to the study, copy in Appendix		
The debrief form is written specific to the study, copy is in Appendix		
The overall risks to research subjects are reasonable in relation to the anticipated benefits		

The risks to research subjects are explained and procedures explain how risk is minimized.		
Adequate provisions are evident to protect the confidentiality of research participant.		
Adequate provisions are evident to store and maintain research data in a confidential space.		
Adequate description of how and when research data will be disposed at the conclusion of the study.		
There are adequate safeguards to protect the rights and welfare of research subjects.		
Format meets appropriate style for headers, margins, spacing and content for all pages of the proposal.		
Format meets appropriate style (i.e. APA Style or other) for citations within all pages of the proposal.		
Format meets appropriate style (i.e. APA Style or other) for list of references.		
All citations within the text are be listed in the references.		
The reference list includes all citations in the text (except when bibliography is utilized)		
Ethical requirements for human participants have been met. (tick if relevant)		
Ethical requirements for animal use have been met.(tick if relevant)		
Ethical requirements for plant use have been met. (tick if relevant)		
Other:		

IERB Primary Reviewer Name: _____Signature: _____Date:_____

APPENDIX D: IERB INFORMED CONSENT FORM SAMPLE-*(AIU/IERB Form 2017-4)*

PARTICIPANT CONSENT FORM

SAMPLE

I am (*Full Name*), a student at Africa International University, where I am pursuing a _____ degree. As part of my degree requirements I am completing a research study and I would like to include you in the study. My research chair at AIU (*insert name and title*) may be contacted by email at (*email address*) or phone (*insert office or cell phone*) if you have any questions at any time.

Your written consent is required to participate so that I can confirm that you have been informed of the study and that you agree to participate. You are free to decline or discontinue your participation at any time during the study if you wish to do so. All information obtained in this study will be kept confidential; a number will be assigned to any research forms to ensure your privacy is protected. Your name or identify will not be given in any report or publication.

The purpose of the research is to gain further understanding of the current experiences of victims of the 2007/2008 post-election violence. You will be asked to complete three forms answering questions about your current emotional experiences. This is not an exam or a test, there is no deception in these questions, and there are no right or wrong answers, simply answer the questions as honestly as you can. The three questionnaire forms should take between 30 minutes but no longer than about 45 minutes to complete in one sitting. A demographic form including your age and other basic information will also be requested.

The outcome of the information obtained during this research will be summarized and utilized in my dissertation study. Participant names will not be utilized, as shown below a number will now be assigned to ensure your identity is kept confidential during and after this study is completed.

My Consent to Participate:
By signing below, I consent to participate in this study.

_____ _____
Signature of Participant Today's Date

_____ _____
Principal Researcher Today's Date

Participant Number to be used on all documents: _____

APPENDIX E-i: INSTRUCTIONS FOR INFORMED ASSENT-*(AIU-A/IERB Form 2017-5)*

This information is for investigator use when developing an assent form.

DO NOT INCLUDE THE INSTRUCTIONS OR CHECKLIST WITH YOUR FINAL ASSENT FORM DOCUMENT FOR PARTICIPANTS OR FOR IERB REVIEW.

The assent form is to be used when participants who, by age or circumstance, are not able to give legally effective informed consent. When legally effective informed consent cannot be obtained, the investigator should obtain the "assent" of the minor or cognitively impaired participant. This is separate from obtaining a parent or guardian's permission for the child to participate (through a Parent/Guardian Informed Consent Form). AIU's IERB require that the written assent of a minor child be sought when the child is between the ages of 7-15 years. Minors between ages 16 and 18 will give written consent in conjunction with the written consent of their parent(s) or legal guardian(s). Minors below the age of 7 will give verbal assent in conjunction with parental or guardian consent.

The assent form documents the minor's or cognitively impaired participant's affirmative agreement, or assent, to participate in a research project. The investigator should respect the decision of a minor or cognitively imparted participate to NOT participate, even when the parent or legally authorized representative is willing to sign the Informed Consent Form.

- For adolescents between the ages of 15 and 17, the assent form should closely follow the consent form used for consenting adult participants.
- For minors between the ages of 11 and 14 and for cognitively impaired individuals, the IERB recommends using a simple written assent form.
- If younger than 11, written assent is not required, but participants should be given an opportunity to decline verbally (where relevant). .
- With the suggestions above, it is very important to use language appropriate to the subject's reading level. Therefore, if your particular subject group would not understand the language used in our sample assent forms, you must use language they will understand. If the subject population includes a wide range of ages it may be necessary to use more than one form**.**
- You must obtain parent/guardian informed consent when using subjects under the age of 18.
- Assent forms should be written in the second person (you statements).
- Assent forms must be free of spelling and grammatical errors. It is important for the participant to fully understand what they are agreeing to do in your research study. A form full of spelling and grammatical errors does not communicate and cannot serve its purpose. Please proofread your informed consent before turning it in to the IERB.
- When appropriate, include the full name of the study sponsor (e.g. National Institute of Health, National Science Foundation).
- Select a font type and size that is easy to read.
- You do not have to use the same format as our sample assent forms, but the general requirements for informed consent and assent must be included.

APPENDIX E-ii INFORMED ASSENT CHECKLIST

The assent form should be simple enough for the child (minor 17 years of age or younger) or a cognitively impaired individual to understand. It should briefly explain and include the following points:

- The individual is being asked to participate in a research study
- Include a general purpose of the research study
- An estimate of how much time is involved in participating
- What will happen to them if they agree to participate (e.g. “answer some questions”)
- The foreseeable risks or discomforts they may experience (immediate risks/discomforts rather than future or theoretical possibilities)
- The benefits which may reasonably be expected from the research
- The individual may ask their parents or the researcher any questions about participating
- The research is voluntary (up to them), and they may stop at any time
- The parent/guardian also will need to grant permission for the individual to participate in the research
- All information provided by the participant in the research study is kept confidential

APPENDIX E-iii: PARENTAL INFORMED CONSENT FORM SAMPLE

You are invited to participate in a research study conducted by (Principal Investigator). The purpose of this research is (explain using language which can be easily understood by the subject). Your child's participation will involve (describe the procedures to be followed). The amount of time required for your child's participation will be (provide an estimate of the expected duration of the child's participation in the study).

There are no known risks associated with this research. OR There are certain risks or discomforts associated with this research. They include (describe any reasonably foreseeable risks or discomforts to the child. You may also describe the measures you will take to minimize these risks and discomforts.)

There are no known benefits to the child that would result from the child's participation in this research. OR (Describe any benefits to the child and to others that may reasonably be expected from the research.) This research may help us to understand (brief statement, if appropriate).

(Describe the extent to which confidentiality of records identifying the child will be maintained. If appropriate, precede the description with: We will do everything we can to protect your child's privacy. If appropriate, follow the description with: Your child's identity will not be revealed in any publication resulting from this study.)

Participation in this research study is voluntary. You may refuse to allow your child to participate or withdraw your child from the study at any time. Your child will not be penalized in any way should you decide not to allow your child to participate or to withdraw your child from this study.

If you have any questions or concerns about this study or if any problems arise, please contact (insert Principal Investigator's name here). If you have any questions or concerns about your child's rights as a research participant, please contact AIU's Institutional Review Board.

Consent

I have read this parental permission form and have been given the opportunity to ask questions. I give my permission for my child to participate in this study.

_____ _____

Parent/Guardian Signature Date

_____ _____

Child's Name Age

_____ _____

Principal Researcher Date

Participant Number to be used on all documents: _____

APPENDIX E- iv: IERB INFORMED ASSENT FORM SAMPLE

FOR PARTICIPANTS AGED 17 YEARS OLD AND BELOW

I am (*Full Name*), a student at Africa International University, where I am pursuing a Doctor of Psychology degree. As part of my degree requirements I am completing a research study and I would like to include you in the study. My research chair at AIU (*insert name and title*) may be contacted by email at (*email address*) or phone (*insert office or cell phone*) if you have any questions at any time.

Your assent or agreement is required to participate so that I can confirm that you have been informed of the study and that you agree to participate. You are free to decline or discontinue your participation at any time during the study if you wish to do so. All information obtained in this study will be kept confidential; a number will be assigned to any research forms to ensure your privacy is protected. Your name or identify will not be given in any report or publication.

The purpose of the research is to gain further understanding of the current experiences of victims of the 2007/2008 post-election violence. You will be asked to complete three forms answering questions about your current emotional experiences. This is not an exam or a test, there is no deception in these questions, and there are no right or wrong answers, simply answer the questions as honestly as you can. The three questionnaire forms should take between 30 minutes but no longer than about 45 minutes to complete in one sitting. A demographic form including your age and other basic information will also be requested.

The outcome of the information obtained during this research will be summarized and utilized in my dissertation study. Participant names will not be utilized, as shown below a number will now be assigned to ensure your identity is kept confidential during and after this study is completed.

My Assent to Participate:
By signing below, I agree to participate in this study.

_____ _____ _____
Signature of Child My Age Date

_____ _____
Parent or Guardian Signature Date

_____ _____
Principal Investigator Date

Participant Number now to be used on all research documents: _____

APPENDIX F: IERB PARTICIPANT DEBRIEF FORM SAMPLE - *(AIU/IERB Form 2017-6)*

The debrief is verbally said to each participant promptly at the conclusion of their part in the study. The following sample debrief language shall be modified according to the type of study and include pertinent referrals or other specific information.

Sample:

Thank you for participating in this research study. The purpose of this study is to gain an understanding of the prevalence of posttraumatic stress disorder and use of alcohol among victims of the 2007/8 post-election violence. Your participation will help researchers gain more insight into the current experiences of victims of the post-election violence.

In the event you have any distressful reactions to the questions presented to you in this study, you may want to seek counseling for support, and a list of counseling referrals if being provided to you, for your reference.

Once again thank you for your participation.

Sincerely,

PI Signature

APPENDIX G-i: IERB CONFIDENTIALITY FORM – *Principal Investigator*

This confidentiality form is a legal agreement between AIU's IERB and the undersigned *principal investigator* who will have access to individually-identifiable original records (electronic or paper), or any other matters regarding the research process.

IERB Research Number: _____

PI Name:_____ Date: _____

Title of Research_____

In conducting this research project, I agree to the following:

1. Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format.
2. Keep all research information in any form or format securely maintained on a daily basis, during the process of conducting and writing the research.
3. At the conclusion of the research, dispose of any documents that contain identification information, such as participant names or other information that could reveal identity of the human subject.
4. Monitor all other researchers who work with me, i.e. research assistants, administrative persons, etc., to ensure their compliance to confidentiality.

Any violation of this agreement would constitute a serious breach of ethical standards, and I pledge not to do so.

Principal Investigator

_____ _____ _____

Print Name Signature Date

_____ _____ _____

Witness Name Signature Date

APPENDIX G-ii: IERB CONFIDENTIALITY FORM – *Other Researchers*

This confidentiality form is a legal agreement between AIU's IERB and the undersigned *other researchers* who will have access to individually-identifiable original records (electronic or paper), or any other matters regarding the research process.

IERB Research Number: _____

Other Researcher's Name:_____ Date: _____

Title of Research_____

In conducting this research project, I agree to the following:

1. Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format.
2. Keep all research information in any form or format securely maintained on a daily basis, during the process of conducting and writing the research.
3. At the conclusion of the research, dispose of any documents that contain identification information, such as participant names or other information that could reveal identity of the human subject; as approved by the principal investigator

Any violation of this agreement would constitute a serious breach of ethical standards, and I pledge not to do so.

Other Researcher:

_____ _____ _____

Print Name Signature Date

_____ _____ _____

Witness Name Signature Date

This study has been reviewed and approved for human subject participation by AIU IERB. If you have questions or concerns about this study, please contact the principal investigator. If you have questions regarding the participant's rights, contact the IERB Office at 0743513617.

APPENDIX G- iii: IERB PROPOSAL CONFIDENTIALITY FORM – *IERB Members*

This confidentiality form is a legal agreement between AIU's IERB and the undersigned *IERB Members* who will have access to individually-identifiable original records (electronic or paper), or any other matters regarding the research process.

IERB Research Number: _____

IERB Member Name: _____ Date: _____

Title of Research_____

In conducting this research project, I agree to the following:

1. Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format, outside of your IERB role.
2. Keep all research information in any form or format securely maintained at all times.
3. At the conclusion of your IERB role, dispose of any documents that contain identification information, such as participant names.

Any violation of this agreement would constitute a serious breach of ethical standards, and I pledge not to do so.

IERB Member:

_____ _____ _____

Print Name Signature Date

_____ _____ _____

Witness Name Signature Date

APPENDIX G-iv: IERB PROPOSAL CONFIDENTIALITY FORM – *Visiting IERB Members*

This confidentiality form is a legal agreement between AIU's IERB and the undersigned *IERB Members* who will have access to individually-identifiable original records (electronic or paper), or any other matters regarding the research process.

IERB Research Number: _____

Visiting IERB Member Name:_____ Date: _____

Title of Research_____

In conducting this research project, I agree to the following:

1. Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format, outside of your IERB role.
2. Keep all research information in any form or format securely maintained at all times.
3. At the conclusion of your IERB role, dispose of any documents that contain identification information, such as participants'names.

Any violation of this agreement would constitute a serious breach of ethical standards, and I pledge not to do so.

Visiting IERB Member:

_____ _____ _____

Print Name Signature Date

_____ _____ _____

Witness Name Signature Date

APPENDIX G-v: IERB PROPOSAL CONFIDENTIALITY FORM – *IERB Office Staff*

This confidentiality form is a legal agreement between AIU's IERB and the undersigned *IERB Office Staff* who will have access to individually-identifiable original records (electronic or paper), or any other matters regarding the research process.

IERB Research Number: _____

IERB Office Staff Name:_____ Date: _____

Title of Research_____

In conducting this research project, I agree to the following:

1. Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format, outside of your IERB role.
2. Keep all research information in any form or format securely maintained at all times.
3. At the conclusion of your IERB role, dispose of any documents that contain identification information, such as participant names.

Any violation of this agreement would constitute a serious breach of ethical standards, and I pledge not to do so.

IERB Office Staff:

_____ _____ _____

Print Name Signature Date

_____ _____ _____

Witness Name Signature Date

APPENDIX H: IERB OPERATIONS DATA SUMMARY FORM

This data collection form shall capture Bi-Weekly, Month to Date (MTD) and Year to Date (YTD) information on the IERB processes. This form is to be updated bi-weekly by the IERB office and forwarded to the IERB Chair.

Part A: Number of Proposals Processed

Total Number of Proposals Received/Processed		**Bi-Weekly**	**MTD**	**YTD**
1	New Proposals Received and Scheduled for IERB Review			
2	Returned NOT-Reviewed (Incomplete submission)			
3	Scheduled for IERB Review			
4	IERB Approved on first submission			
5	Returned by IERB for Re-submission with corrections			
6	Re-submissions by PI and scheduled for IERB review			
7	IERB Approved after Re-submission			
8	Deferred by IERB			

Comments:_____

_____

_____

_____

Part B: IERB Activity

Total Number of IERB Review Meetings		Bi-Weekly	MTD	YTD
1	Number Meetings Scheduled			
2	Number Meetings Held			
3	Number Postponed due to no quorum			
4	Number Postponed due to IERB Chair direction			

Comments:_____
_____
_____

APPENDIX H: IERB OPERATIONS DATA SUMMARY FORM

Part C. Member Participation Summary

IERB Member Name		*Number of IERB Meetings Attended*			*Number Attended as an Assigned Primary Reviewer*			*Total Attended As Member and Primary Reviewer*
		Bi-Weekly	**MTD**	**YTD**	**Bi-Weekly**	**MTD**	**YTD**	**YTD**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								

14								
15								
16								
17								
18								
19								
20								
21								

Comments:

APPENDIX I: IERB TRAINING SUMMARY FORM

Training Activities: Weekly, Monthly (MTD), Yearly (YTD)

Title of Training		Name of Team Leader /Trainer	Number Trainings This Week	Number MTD	Number YTD
1					
2					
3					
4					
6					
7					
8					
9					
10					
11					
12					

Comments:

IERB Training for IERB Certification Name of Participant		Date(s) of Training	Trainer/ Team Leader	Number of Scheduled Non-IERB Member Participants	Number of Actual Completed New IERB Member Certifications
1					
2					
3					
4					
6					
9					
10					

Comments:

_____

APPENDIX J: IERB MEMBERSHIP SUMMARY FORM

Current IERB Membership Listing:

No.	IERB Member Names	Email Address	Cell Phone	Start Date of 4 year IERB Term	Completion Date of 4 year IERB Term
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
18					
19					

Changes in Membership:

IERB Member Name		Effective Date	New Member	Term Completed	Retired	Resigned	Dismissed

Comments:

_____

_____

Signed

Prof. Samuel Katia Deputy Vice-Chancellor Academic Affairs & Research Africa International University	Prof. Dankit Nassiuma Vice-Chancellor Africa International University