

APPENDIX A: IERB PROPOSAL SUBMISSION FORM

Part B: Principle 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' Signed Confidentiality Agreements
- 4 Hard Copies of all submission documents
- 1 Soft Copy of all submission documents
- Receipt of payment

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 **(+254743513617)** immediately, and by email to joash.mutua@africainternational.edu within twenty four (24) hours after the PI is aware of the event.

Principal Investigator Signature	Date