Atlantic Center for Research andEvaluation
Institutional Review Board (ACRE IRB)

POLICIES & PROCEDURES HANDBOOK

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Foreword

The objective of this Standard Operating Procedure (SOP) is to ensure quality and consistency in the review of social, behavioral, clinical and biomedical research protocols that are consistent with the Council for International Organizations of Medical Sciences (CIOMS) and the national ethical guidelines for research on human subjects. Institutional Review Boards (IRBs) should provide independent, competent and timely review of ethical issues prior to the commencement of research studies, including the regular monitoring and evaluating of ongoing studies.

IRBs review and approve all research proposals involving human participants with a view to safeguarding the dignity, rights, safety and well-being of research participants, irrespective of the funding source. The goals of research, however important, should never be permitted to override the health and well-being of research subjects.

The Atlantic Center for Research and Evaluation (ACRE) Africa Center Institutional Review Board was therefore instituted to tackle social, cultural and other ethical issues in human subject research by instituting internationally acceptable principles and practices. The IRB will ensure that all cardinal principles of research ethics (i.e., autonomy, beneficence, non–malfeasance and justice) are considered during research project-related planning, implementation and reporting. It examinesthe informed consent process, the risk-benefit ratio, the distribution of burden/benefit and the provisions for appropriate compensations, wherever required. It reviews proposals prior to the commencement of research studies, as well as, monitors research projects through site visits and periodic reports, etc. The IRBalso ensures compliance with all regulatory requirements, applicable guidelines and laws.

With an increasing trend in international collaborative research between external and local institutions, interpretations of ethical issues may vary. As such, there is a need for standardized regulations of research activities through established IRBs at recognized institutions, including emerging IRBs in Liberia.

Most importantly, the need for SOPs cannot be overemphasized to ensure consistency in regulatory requirements. While emerging ethical issues in post-conflict environments will require updates to SOPs, it is essential that changes are consistent with internationally acceptable best practices in human subject research.

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Article I. Introduction

The ACRE IRB (Atlantic Center for Research and Evaluation Institutional Review Board) is available to persons or institutions interested in research work regarding the protectionof human subjects in health or the social sciences in Liberia. It exposes people to new ideas in a wide range of scientific fields, and the decisions and opinions they bring to bear in the area of research. It has implications for individuals and institutions who conduct research activities as well as those who participate in research activities in Liberia.

Article II. Mission

The mission of ACRE IRB is to help researchers conduct important studies in a way that protects the rights and welfare of research participants. People who do not understand how the IRB should function may think that making IRB determinations requires little more than common sense and good intentions. This is often not the case. As you learn more about research ethics and research regulations, you will understand that many research projects present ethical issues that are not simple to recognize or resolve.

Article III. Policy

It is the policy of the Atlantic Center for Research & Evaluation (ACRE) Institutional Review Board (IRB) to assure unbiased review ofall research proposals submitted and to inform the Principal Investigator(s) of such proposals of the results of the review.

This Policies and Procedures Handbook provides information on a structured approach to evaluating the ethics of research protocols and a clear understanding of the fundamental principles that should be used to determine or accept research proposals.

Article IV. Procedures

1. All research proposals submitted by any investigator, training institutions, organizations or ministries, etc., would be reviewed in a standard manner.
2. All research proposals are to be submitted (either via electronic mail or in person) to The IRB Coordinator, ACRE, Ground Floor, Graduate School Building, University of Liberia, Capitol Hill, Monrovia, Liberia. Proposals submitted electronically should be sent to thefollowing addresses: < *jktegli@yahoo.com* > and < *ulpireirb@gmail.com* >. Details concerning the number of copies to submit can be found in the application package.
3. Principal investigators are required to submit materials four (4) weeks in advance of the date that a decision is requested. In the case of Full Review Studies (see IRB Application Guidelines), submission is required four (4) weeks prior to the next scheduled IRB meeting: Contact email addresses provided above. The IRB will convene a special meeting, if necessary, to accommodate the Principal Investigator's compliance with an external funding deadline; however, submission is required four (4) weeks prior to the special meeting date.
4. On receipt of a proposal for review, the Secretariat will preliminarily assess the completeness of the submission. If the submission is incomplete, the Secretariat will so inform the principal investigator and request the additional materials. Once the submission is deemed complete, the Secretariat will so advise the principal investigator and will distribute the materials to the assigned members of the IRB. Exempt studies will be reviewed by all members of the IRB; expedited studies will be reviewed by all members of the IRB; full review studies will be sent to the entire IRB membership for review.

5. The Secretariat logs in all submitted proposals and maintains this log for all proposals. The log entry for each proposal includes: the IRB code number (assigned by the Secretary); the name of the principal investigator; the title of the proposal; a brief description of the proposal that specifies the intervention or hypothesis to be tested or, in the case of qualitative proposals, the method for data collection and analysis; the assignment of the proposal for exempt, expedited, or full review; the dates of IRB review; a summary of action taken by the IRB; the date of enrollment of the first subject; and the date for annual IRB review.
6. The IRB member(s) will perform the initial review of each proposal, including the assessment of the completeness, clarity, scientific merit, risk/benefit, and ethical propriety of the proposal. If the proposal is deemed exempt or expedited, the Secretariat will so notify the principal investigator.
7. If the proposal is deemed to require a full review, the principal investigator will be required to submit additional copies of the proposal to be forwarded to the entire IRB membership by the Secretariat. The complete proposal will be reviewed by the entire IRB membership. The IRB Chair will communicate in writing the results of the IRB review to the principal investigator.
8. The Secretariat will maintain complete files of all proposals submitted and all correspondence and other documentation pertaining to each proposal.
9. On a quarterly basis, the Secretariat will report on the full IRB documentation of all logged proposals for that quarter, using the "Log of Proposals Received."
10. The Secretariat will periodically notify Investigators about required reports and study closure.

Article V. Application Guidelines

The ACRE IRB is mandated by the Board of Directors of ACRE Africa Center. Its purpose is to review and certify the ethical acceptability of all research involving human participants conducted in Liberia. All studies submitted to ACRE IRB shall be approved by members of the Board. This includes all studies conducted by ACRE investigators as well as all research by outside investigators or students and faculty of universities in Liberia. Before submitting a proposal for review, the PI must check the level at which the protocol will be reviewed (Articles XII – XVIII) and confirms the documents that will be needed (see Article IX, Section 9) of the handbook.

Article VI. IRB MEMBERSHIP

Section 6.01 Composition of the Board

The IRB shall comprise of 12 members with the qualifications and experience, individually and collectively, to review and evaluate the science, medical and ethical aspects of research protocols submitted. The membership shall include both scientists and nonscientists from diverse backgrounds to undertake impartial and adequate review of research proposals.

The IRB membership shall be broken down as follows:

I. Scientists
    a. Including but not limited to natural science, social science and behavioral science.
II. Non-scientists
    a. Health practitioners
    b. Legal experts representing the community
    c. Civil society

The IRB shall ensure social inclusivity and gender sensitivity in its membership and recruitment of ad hoc reviewers. There shall be adequate representation by age, gender, community, etc., on the Board to safeguard the interests and welfare of all segments of the society. Members of the IRB shall be drawn from both public and private institutions within the country.

Section 6.02 Appointments

Members of the IRB (full, regular and ad hoc) shall be recommended by the IRB Chair and appointed by the ACRE Board of Directors.

Section 6.03 Tenure of IRB Members

Members of the IRB shall be appointed initially for a term of three (3) years which shall be renewable subject to ACRE Board of Directors' decision. To maintain continuity in the operations of the Board, at least one-third of the membership shall be retained at any given time. The outgoing Chair shall be an ex-officio member on the incoming Board.

Section 6.04 Term of Reference of the IRB

1) The Board shall review human subject research proposals submitted to it within a reasonable time and document its findings in writing to the applicant(s) or investigator(s).
2) The Board shall safeguard the dignity, rights, safety, and well-being of all study participants/subjects and communities, paying special attention to studies that involve vulnerable participants (i.e., children, pregnant women, prisoners, etc.).
3) The Board may request the principal investigator(s) to explain any aspect of the study that may require personal appearance at its meeting.
4) The Board shall provide standardized guidelines and forms for the submissions of research proposals.

Section 6.05 Qualification of Investigators

The Board shall consider the suitability of the investigator(s) for the proposed study with respect to relevant qualification, training and/or experience, as documented by a current curriculum vitae and/or any other relevant documentation.

Section 6.06 Benefits of Participants

The Board shall review both the amount and type of benefit to participants to ensure that it does not present problems, coercion or undue influence on study participants.

Section 6.07 SOPs for Review

The IRB members and consultant reviewers shall be provided all relevant SOPs by the Secretariat to guide in the review process of all submitted protocols.

Section 6.08 Previously Reviewed and Approved Protocols

Submitted proposals that have been reviewed elsewhere shall be reviewed afresh by the Board.

Section 6.09 Meeting Time

The date of meetings will be provided to applicant(s)/investigator(s) who shall be available to offer clarifications, if necessary.

Section 6.10 Review of SOP

The SOPs shall be revised every three years.

Section 6.11 Resignations and Removals

1) IRB Members may resign from the IRB by submitting a letter of resignation to the Chair of the IRB who shall inform the ACRE Board of Directors and IRB Coordinator for a replacement.

2) The Executive Committee in consultation with the Coordinator shall request for a replacement of any Board member as a result of the following:
   a) Protracted illness of a member that does not permit him/her to participate in Board deliberations.
   b) Persistent absenteeism (five consecutive absences) of a member without reasonable cause.
   c) Voluntary withdrawal by a member.
   d) Unethical conduct such as continued breach of Confidentiality of Board deliberations and other matters.

Section 6.12 Structure (see annex)

Section 6.13 Compensation/Allowances for IRB Members

Regular voting Board members as well as independent consulting members may be modestly compensated for the time spent on IRB-related activities. The amount of such compensation will be determined by the Coordinator in consultation with the Chair of the Board.

Section 6.14 Protocol Review Fees

Fees are payable for protocol submissions. Additional fees may be charged for amendments, particularly those of a substantive nature. The Coordinator and the Chair of the Board shall determine the amount for protocol review. (See annex for payment structure)

A relatively minimum submission fee will be required for non-sponsored research conducted by individual investigators (50% of sponsored research).

Section 6.15 Board of Directors

Provides oversight and approves all guidelines, SOP and policies of the IRB.

Section 6.16 IRB Executive Committee

The IRB Executive Committee shall comprise of the Coordinator, the Chair, and two members of the IRB recommended by the Chair in consultation with the Coordinator. The Executive Committee is delegated to undertake expedited review and approval of business that does not require full Board review such as low and negligible risk research applications, amendments to current IRB approved research projects, annual progress reports and final reports, etc.

1) Meetings
   a) The Executive Committee shall be chaired by the Chair. The Coordinator takes responsibility in the absence of the Chair. In the absence of both, the Chair shall designate.
   b) The Executive Committee shall meet quarterly and shall be scheduled by the coordinator.
   c) Minutes of meetings shall be recorded by the Secretary of the Board.
   d) The quorum for a meeting shall be two-third of the voting membership.
   Minutes will be reviewed by the Coordinator and distributed to the committee members prior to the next convened meeting.

2) Finalization and Dissemination of SOPs
   a) The ACRE Board of Directors Chair shall sign updated and approved SOPs.
   b) The IRB Coordinator will ensure that updated and approved SOPs are published on the ACRE website (www.ACREafrica.org).

Article VII. ADMINISTRATION AND FUNCTIONS OF THE IRB

Section 7.01 The Secretariat and Officers

The IRB Secretariat shall constitute the following but not limited to the Coordinator, IT Officer and Finance Officer.

Section 7.02 Functions of the Secretariat

The functions of the secretariat shall include but not limited to the following:

1) Prepare, maintain, and distribute study files.
2) Organize Committee meetings regularly as per the IRB calendar.
3) Prepare and maintain meeting agendas and minutes.
4) Keep and maintain the IRB documentation and archive.
5) Communicate with the IRB members and applicants.
6) Arrange for training of personnel and IRB members.
7) Organize the preparation, review, revision and distribution of SOPs and guidelines.
8) Provide the necessary administrative support to the Chair in all activities relating to the IRB, such as communicating a decision to the applicant.

9) Provide to the IRB updates on relevant and current issues, including literature related to ethics in research.

Section 7.03 Responsibilities of the Secretary

The responsibilities of the secretary shall include:

1) Having custody of IRB documents, records and archives.
2) Prior-review of each protocol submission to ensure adherence to submission requirements.
3) Ensuring new and continuing IRB members are provided training/education on issues related to ethics of human research.
4) Designing and disseminating templates for the IRB submission documents, including research protocols, informed consent materials, agreements and periodic and final reports.
5) Designing and maintaining a system for collecting and filing all IRB documents, including meeting minutes, member qualifications, protocol submission versions, deviations from approved protocols, and periodic and final reports.
6) Preparing and submitting annual IRB operational budgets and plan to the ACRE Board in consultation with the Chair.
7) Accepting, verifying, duplicating, and distributing all submitted items to the IRB members for review.
8) Creating and distributing meeting agendas and arranging meeting logistics.
9) Attending Committee meetings, taking minutes during the meetings, and verifying and distributing minutes in a timely manner.
10) Corresponding with all submitting researchers at all times throughout the submission and review process.
11) Advising investigators on the preparation and submission of protocols for IRB review.
12) Assisting the Chair to conduct IRB meetings.
13) Continually studying and updating staff about IRB operational regulations.

Section 7.04 Responsibilities of the Coordinator

The responsibilities of the coordinator shall include:

1) Shall call meetings in consultation with the Chair.
2) Shall receive proposals/protocols.
3) Shall dispatch proposals for scientific review to selected reviewers.
4) Shall prepare proposal review documents for discussions at regular IRB meetings.
5) Shall undertake all other administrative duties as assigned by the Chair
6) Shall explore capacity building opportunities for IRB members

Section 7.05 Responsibilities of the Chair

1) Shall be the head and chief spokesperson of the IRB and shall conduct meetings in accordance with the policies regulations and timetable approved by the IRB.
2) Shall facilitate the provision of training and educational programs for new and continuing IRB members.

3) Shall oversee the functions and activities of the Secretariat, ensuring that the Secretary performs his /her tasks effectively and efficiently.
4) Shall assign responsibilities and duties to any member of the IRB as deem necessary.
5) Shall review and accept revisions made based on the IRB recommendations, pending protocol approval.
6) Shall determine submissions that could be exempted from review, or expedited review, and notify the IRB and the submitting Principal Investigators.

Section 7.06 Responsibilities of the IRB Members

1) Review, discuss and consider research protocols submitted to the IRB for evaluation in order to safeguard the rights, safety, and well-being of study participants.
2) Review progress reports and monitor ongoing research studies appropriately.
3) Evaluate final reports and outcomes.
4) Maintain absolute confidentiality of all documents and deliberations of IRB meetings.
5) State conflict of interest, where applicable.
6) Assume duties as assigned to them by the Chair of the IRB.
7) Participate in a subcommittee of the IRB as a service on behalf of the IRB (*ad hoc* service).
8) Attend meetings regularly and actively participate during deliberations.

Article VIII. IRB MEETING ADMINISTRATION

Section 8.01 Frequency

The IRB shall convene a meeting every month or when deemed necessary.

Section 8.02 Quorum

A quorum shall be greater than 50% of the voting members of the IRB at any given event. A quorum shall consist of regular and/or alternate members (persons formally selected by the IRB to substitute for regular member(s) who is/are unavailable during a meeting) of the Board and shall include at least one member whose primary background is scientific related, one member whose primary background is non-scientific related areas. Special/independent consultants cannot be used to establish a quorum. Members who are recused from the review of a protocol cannot be used to establish a quorum.

Section 8.03 Independent Consultants

The IRB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals will be required to sign a confidentiality agreement before they review a protocol or attend an IRB protocol discussion. They shall not vote. The consultant will provide the IRB Chair with a written report to be shared with all reviewers summarizing relevant information.

Section 8.04 Meeting Procedure

The Chair, or a delegated member of the IRB, shall call the meeting to order provided there is a quorum. If there is no quorum, the meeting shall be rescheduled.

(a) Meeting agenda

The Chair shall follow the agenda to conduct the meeting but may decide to deviate from the agenda based on personal judgement. The meeting shall most likely follow the order below:

1) Adoption of the agenda;
2) Confirmation of minutes of the previous meeting;
3) Matters arising from previous minutes;
4) Discussion of new agendas;
5) Action items (voting on protocols, acceptance of serious adverse events, periodic and annual reports, final reports, etc.);
6) Any other business (AOB).

(b) Presentation by investigator(s)

If the meeting is a full review of a new protocol submission, then the principal investigator of that protocol will be invited by the IRB during deliberations on said protocol to answer questions or queries that may be raised by the IRB members but must go out when final decisions are being made on the protocol by IRB members.

(c) Minutes of the Meeting

During IRB meetings, all deliberations shall be recorded either electronically or written manually. The minutes of the meeting shall include a list of attendees, absentees, agenda items, matters arising from previous minutes and action taken by the IRB; decisions or votes on those matters, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving a research proposal; and a written summary of the discussion of issues and their resolution.

(d) Summary of protocols

The Secretary shall also include a summary of each protocol that has been considered for approval.

(e) Review and approval of minutes

The Secretary shall produce a hard copy of the minutes, sign, and distribute it to all IRB members, along with a copy of the next meeting's agenda about a week prior to the next scheduled meeting. The IRB members shall read and ensure that minutes are accurate per the deliberations. The Chair of the IRB shall confirm the accuracy and completeness of the minutes by signing, and archiving them, together with the meeting's agenda and other relevant attachments.

Article IX. PROTOCOL REVIEW PROCEDURE

Section 9.01 Submission of Application

The Principal Investigator (PI) shall submit to the Secretary of the IRB, an application for review and approval of a research protocol along with the following documents:

1) Covering letter.
2) Summary of the study protocol (ACRE IRB template).

3) Submission of the detailed protocol and / or amendments, including data collection instruments, surveys, tests, questionnaires, debriefing information, etc.
4) Study brochure, where applicable.
5) Evidence of submission and / or approval from other IRBs, where applicable.
6) Evidence of research ethics training (i.e., certificate in human subject protection) of the research team members.
7) Questionnaires/other study instruments, where applicable.
8) Informed Consent forms, where applicable.
9) Records of Data Safety and Monitoring Board (DSMB) and Institutional Biosafety Committee (IBC), if applicable.
10) Record of Material Transfer Agreement (MTA), if applicable.
11) Status report for ongoing study (applicable for continuing review).
12) Letter of collaboration or support with collaborating entity/researcher(s), if applicable.
13) Capacity building plan for collaborating agency/researcher, if applicable.
14) Curriculum Vitae of investigators/researchers.
15) Social corporate responsibility plan for communities, if applicable.
16) If the research or the recruitment will take place in or through schools, businesses, care facilities or other organizations, a letter from an appropriate official permitting the conduct of the research activities on their premises should be included.
17) Budget.

Section 9.02 Review process

(a) Determination for full or expedited review

The Coordinator in consultation with the IRB Chair shall determine if a protocol submission qualifies for expedited review. If this is the case, then, the reviewer(s) shall be appointed to review the protocol.

(b) Participation of principal investigator in a review

The Secretariat shall inform the PIs of the scheduled meeting to consider their protocol submissions at least two weeks in advance. The PI may be invited into the meeting room during consideration of his/her protocol to make a presentation on the protocol being reviewed. After the presentation, the PI shall remain to answer any questions/queries, concerns, and suggestions from IRB members. A co-investigator/researcher may attend the meeting on the PI's behalf if necessary. Following the question and answer session, the PI and any other persons with a conflict of interest in the protocol shall leave the meeting room while a vote is being taken.

(c) Voting

Each IRB member shall vote for or against a protocol or abstain. An absentee member may be allowed to send in his/her comments on the protocol but cannot vote. A protocol shall be approved, when a simple majority of the IRB members in attendance agree via their votes. The IRB may also decide to postpone decisions on a protocol if more information or consideration is required. After voting on a protocol submission, the IRB may invite the PI back into the meeting room for immediate notification of the voting results.

(d) Methods of communicating decision to investigator(s)

All decisions shall be communicated to investigators in writing. In the case where the IRB disapproves a research proposal, it shall provide the reasons for such decision and shall give the investigator an opportunity to respond in person or in writing.

Section 9.03 Assessment of a Study Protocol

The following aspects of the study shall be considered during the assessment of submitted protocols:

(a) Study Design

The study design shall be reviewed with a view of evaluating the need for human participants for the study, objectives of the study, rationale, beneficence, adequacy in literature review, appropriateness of the methodology proposed, inclusion / exclusion criteria, control arms (where necessary) and withdrawal or discontinuation criteria.

(b) Qualification of Investigators and Study Sites

The qualifications of the investigators shall be scrutinized to see whether their specialization and training background match the demands of the study. The study sites shall also be examined for suitability of the study in terms of geographical distribution of the problem under study, facilities and infrastructure, accessibility, and availability of the study sites to accommodate the study. Disclosure of potential conflicts of interest shall also be examined.

(c) Study Participation

The IRB shall assess to ensure voluntary, non-coercive recruitment of subjects for participation. The following shall be evaluated to ensure that they have been adequately considered in the protocol:

1. Procedures for obtaining informed consent.
2. Content of the participant information sheet.
3. Content and language of the informed consent document.
4. Translation of the informed consent document into the local language.
5. The language used in the documents should be Simple relative to the understanding level of the general public.
6. Contact persons with their addresses and telephone numbers (for both the Study Team and the IRB).
7. Privacy and confidentiality.
8. Risks (physical, mental, social).
9. Benefits to participants and to others.
10. Compensation (reasonable / unreasonable).
11. Involvement of vulnerable participants.
12. Provision for medical / psychosocial support.
13. Treatment for study related injuries.
14. Use of biological materials.

Section 9.04 Biological specimens

The following shall be required:

1. A full description of any specimens that will be collected (blood, body fluids, tissue biopsies, etc.).
2. Plans for obtaining consent and clearance from participants and IRB, for long-term storage, export, and future research.
3. Arrangements for transfer and disposal.
4. Community considerations.
5. The impact and relevance of the research on the local community from where the research participants are recruited as well as the wider communities and the environment of concern.
6. The consultation procedures with the concerned communities at the time of the planning and designing the research.
7. The influence of the community on the consent of the research subjects/individuals.
8. Proposed community consultation during the course of the research.
9. The extent to which the research contributes to capacity-building, such as the improvement of local healthcare, research, and the ability to respond to public health needs.
10. Description of how the research results will be made available to the research subjects and the concerned communities.

Section 9.05 Voters eligibility

(a) Conflict of interest

IRB Members with conflict of interest will recuse themselves from the review of submissions with which they have a conflict of interest, except to answer specific questions posed by the IRB. They will not participate in voting and will not be counted in the determination of quorum.

(b) Majority vote

A majority (greater than 50%) of members must vote in favor of an action for that action to be accepted by the IRB. Only regular members, and designated alternate (secretary of the IRB and/ or a member of a partner IRB) Members acting in place of regular members, may vote.

(c) Losing quorum during meeting

If quorum is lost during a meeting, through member(s) leaving the room, the IRB shall not take votes until quorum is restored.

Article X. DOCUMENTATION AND RECORDS MANAGEMENT

Section 10.016.1 Document Retention

(a) Study-specific documents

These include study documents specific to the IRB activities and shall include the following:

1. Copies of all original research protocols reviewed, scientific evaluations, if any, that accompanied the proposals, approved sample consent documents, progress reports submitted by Investigators, and reports of adverse events occurring to subjects, and reported deviations from the protocol.
2. Copies of communication between the IRB and Principal Investigators relevant to the study risks and clarifications (e.g., minutes, e-mails, memos, etc.).
3. Reports of any complaints received from subjects.

(b) 6.1.2 Administrative Documents

These include documents of the internal operations of the Atlantic Center for Research & Evaluation (ACRE IRB) as follow:

1. Agendas and Minutes of all IRB meetings showing attendance at meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research; and a written summary of the discussion of refuted issues and their resolutions.
2. A current list of IRB members by names, earned degrees/qualifications, representative capacity on the IRB, experience, and any employment or other relationship between each member and the institution (for example, full-time employee, part-time employee, paid or unpaid consultant, etc.).
3. Copies of all required policies and procedures of the IRB.

(c) Duration of Retention

1. All records regarding a research application (regardless of whether it is approved) shall be retained for at least three (3) years.
2. All records regarding all applications that are approved, and the research initiated shall be retained for at least three (3) years after completion of the research.
3. Denied applications will be treated as terminated files and records shall be retained for three (3) years after the denial of the research.

(d) Manner of Retention

The ACRE IRB has a US Federal-wide assurance number and subscribes to US ethics regulations in addition to research ethics regulations and relevant laws of the Republic of Liberia. The relevant Liberian laws and regulations shall supersede any US regulation that is found to be in contravention during the assessment of a protocol. US Federal IRB regulations permit records to be stored either electronically or in hard copy. The ACRE IRB secretariat shall retain documentation both in electronic format, and in hard copy as deemed feasible.

(e) Disposal of Materials

IRB members are required to return, destroy, and/or delete all IRB-related research protocol review materials that are considered confidential and in excess of the required original documentation.

Article XI. STUDY CLOSURE

Section 11.01Requirements to close a study

A research study is closed under the following circumstances:

1. When no further interventions/interactions with subjects, no follow-ups, nor access to personal identifiable information for research purposes are taking place.
2. When all data analysis of the study is complete, or data have been de-identified and no direct identifiers or code keys (if data are coded) exist that would allow for potential identification of subjects, and
3. Grant funds associated with the protocol are no longer being accessed; or an associated grant remains active, but the human subject research activities have ended.

Section 11.02 Procedures to close a study

A protocol for IRB reviewed research can be closed by Investigators by submitting study closure materials through the electronic system before the expiration of IRB approval. In the case where protocols are transferred to another IRB, they are considered closed once the new IRB assumes jurisdiction.

Section 11.03 Administrative Closure of Protocols

Approved protocols that have gone beyond their end date may be closed administratively by the IRB if the Investigator does not renew the protocol in accordance with the established renewal procedures.

Section 11.04 Reactivation of a Closed Protocol

An Investigator shall have up to 60 days after the date of closure of a protocol to notify the IRB Office of a mistaken closure of a protocol and request reactivation. Once an Investigator requests reactivation, continuing review is conducted on the protocol.

To facilitate this process, the investigator must submit any continuing review materials requested by the IRB to complete the continuing review. Protocols cannot be reactivated if its expiration period is longer than 60 days. In this case, the Investigator must submit a new protocol application.

Section 11.05 Investigator Duties after Protocol Closure

Research records of a research protocol must be retained by the investigator(s) for a period of no more than five (5) years after the closure date. If other regulations and policies apply to a particular protocol, duration of retention of the protocol is in accordance to such regulations/policies.

Though a research protocol has been closed, the Investigators should keep the data they collected, including identifiable private data, in a manner consistent with the IRB- approved protocol and subject consent. Investigators must continue to honor any confidentiality protections of the data.

Investigators must honor any other commitments agreed to as part of the approved research, for example, providing information about the study results to research subjects, commitment to research subjects for use of sample or data in future research, and commitments for compensation to research subjects for research participation.

Article XII. DETERMINATION OF HUMAN SUBJECTS RESEARCH

Section 12.01 Guidelines

The following guidelines have been developed to assist Investigators in determining which activities are subject to IRB review:

1. Any activity that qualifies as research and includes one or more human subjects must be reviewed and approved or declared exempt by the IRB prior to the commencement of the study.

2. Human Subject Research activities may be reviewed by the IRB irrespective of funding.

Article XIII. EXEMPTION DETERMINATIONS

Section 13.01 Exempt Research Activities

A research protocol is considered "Exempt" when it satisfies the following ethical standards:

1. The research in question has no more than minimal risk to participants.
2. Selection of research participants is equitable.
3. There are adequate provisions that the confidentiality of the data will be maintained, where identifiable information is recorded.
4. If there are interactions with participants, the IRB should establish whether there should be a consent process that will disclose the following:
    a. That the activity involves research.
    b. A full description of the procedures.
    c. That subjects' participation is voluntary.
    d. Name and contact information for the researcher.
5. Research involving normal educational practices, conducted in established or accepted educational settings, such as:
    a. Research on regular and special educational instructional strategies, or
    b. Research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.
6. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    a. Information obtained is recorded in such that human subjects are identifiable directly or through identifiers linked to the subjects; and
    b. Any leakage of research participants' responses to outsiders could place the subjects at risk, hence, negatively impacting on his/her employment, etc.
7. If a research study involves the collection of existing data, documents, records, pathological specimens, or diagnostic specimens, that are available publicly or if the information is recorded by the investigator in a way that the subjects are not identifiable directly or through identifiers linked to them.

Article XIV. INITIAL REVIEW

Section 14.01Submission Requirements

Investigators applying for initial review are required to provide necessary documents mentioned in Article IV.

Section 14.02 Review Procedures for Initial Review

1. The Secretary in consultation with the Coordinator shall review the protocol submission by the Investigator for assurance that it contains all of the necessary paperwork and supporting documents.

2. The Coordinator in consultation with the Chair shall determine if the protocol application qualifies for expedited or a full review.
3. Once the protocol application is confirmed complete, copies are distributed to all IRB Members for expedited, continuing or full review procedures.
4. The Secretary shall compile questions and comments received from IRB members and forward them to the Investigator requesting a response to the comments.

Section 14.03 Review Criteria

The IRB will conduct a review of the research which includes, but is not limited to, the criteria outlined in 45 CFR 46.111 and/or 21 CFR 56.111 of the FWA (see annex):

1. A determination that risks to participants are minimal.
2. A determination that risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge expected as a result of the study.
3. A determination that selection of participants is equitable.
4. A determination that informed consent will be sought from each prospective participant or the participant's legally authorized representative (LAR), in accordance with and as required by 46 CFR 46.116 and/or 21 CFR 50.
   A determination that informed consent will be appropriately documented, in accordance with and as required by 46.117 and/or 21 CFR 50.27.
5. A determination that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
6. A determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. A determination that when some or all subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of subjects.
8. A determination of the scientific or scholarly validity of the research. The IRB may consult with subject matter experts as deemed necessary.

Section 14.04 IRB Convened Meeting

At a convened meeting, the IRB will conduct an initial review of the protocol in accordance with the review criteria (Section 9.03: Review Criteria). If the Investigator accepted the IRB's invitation to attend the meeting, she/he will be given the opportunity to answer the IRB's questions and clarify any concerns regarding her/his protocol application. After the Investigator has addressed questions and concerns and has left the meeting, the IRB shall deliberate on the protocol, make findings as appropriate, and decide on an action.

Section 14.05 Review determinations

The IRB may make one of the following determinations as a result of its review of research submitted for initial review:

(a) Approval

The protocol and accompanying documents are approved as submitted. IRB approval will commence on the day the study is approved and expire within a defined time period based on risk assessment and regulations. If specific conditions are stipulated in the approval letter, those conditions must be met by the designated date or approval may be withdrawn.

(b) Approval with Specific Minor Revisions

Minor modifications of, or addition to, a protocol or accompanying document(s) is required. The Investigator will be informed in writing of the required changes and requested information and must provide the IRB with the changes or information.

(c) Tabled

Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator. The proposal is assigned for review at a specific, future meeting.

(d) Deferred

Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator. The proposal is postponed to an unspecific future meeting.

(e) Disapproval

The proposal fails to meet one or more criteria used by the IRB for approval of research. This disapproval determination cannot be made through the expedited review mechanism and may only be made by majority vote at a convened meeting of the IRB.

Section 14.06 Communicating decision to investigators

If a protocol is approved, the IRB Chair or designee will document the approval by signing the Protocol Review Form and an approval letter is written, signed by the IRB Chair, and sent by the secretariat to the Investigator.

The Investigator shall be notified via correspondence if the protocol is approved with specific minor revisions, if substantive revisions are requested, if the protocol is deferred, and if the protocol is disapproved. Once the protocol is revised by the Investigator in response to the IRB concerns, the Chair or designee may approve the protocol by signing the Protocol Review Form and then by an approval letter to the Investigator (in cases of approval with specific minor revisions, substantive review requirement, and protocol deferment).

Where the protocol is disapproved, the Investigator is notified via mail indicating reasons for IRB disapproval and instructs the investigator to respond in writing to the determination within 30 days of the notification. The Investigators may appeal the revisions required by the IRB in writing to the IRB. Appeals will be reviewed in a full IRB convened meeting and if the appeal is denied and the study disapproved, the decision is final. IRB decisions to deny research protocols shall not be overturned by any other authority.

Article XV. EXPEDITED REVIEW

An expedited review involves procedures for certain categories of research which do not require review by a convened quorum of the IRB. After the Secretariat reviews and establishes that a protocol application meets the requirements for expedited review, it is given to an IRB member designated by the Chair to conduct an expedited review. The IRB member will review the research protocol considering but not limited to the following criteria (45 CFR 46.111 and/or 21 CFR 56.111):

1. A determination that risks to participants are minimized.
2. A determination that risks to participants are reasonable in relation to anticipated benefits, if any and the importance of the knowledge that may be expected.
3. A determination that participants' selection is equitable.
4. A determination that informed consent will be sought from each prospective participant or the participant's legally authorized representative (LAR), in accordance with CFR 46.116 and/or 21 CFR 50.
5. A determination that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
6. A determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. A determination that when some or all subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, etc.), additional safeguards have been included in the study to protect the rights and welfare of the subjects.
8. Determination of the scientific or scholarly validity of the research as follow:
    a. The validity is determined by the experience of an investigator,
    b. a review by a funding agency,
    c. a separate peer review process, or
    d. by a thesis/ dissertation committee (for graduate student research).

    These processes help to ensure that, should IRB Reviewers disagree with the scientific or scholarly validity assessment, the application should be reviewed either by an IRB member with appropriate expertise or a consultant whose expertise is germane to the research.
9. The Designated IRB Reviewers may submit their individual questions/queries, concerns, suggestions to the Secretariat in writing, who in terms will compile the findings and submit to the PI for redress.
10. If the corrected protocol submitted by the PI addresses the concerns of the IRB Reviewer(s), the Chair or his/her designee would send a written and signed approval letter to the PI through the Coordinator.

Article XVI. CONTINUING REVIEW

Continuing review is conducted to review progress of an ongoing study and not just changes made in the study in order to ensure continued protection of the rights and welfare of research subjects.

Section 16.01 Submission Requirements for Continuing Review

1. A Completed Continuing Review form;
2. A copy of the current informed consent document(s) or any newly proposed consent document(s) if enrollment is ongoing;

3. A copy of current recruitment material(s) or any newly proposed recruitment material(s) if enrollment is ongoing;
4. A summary of adverse events and any unanticipated problems involving risks to subjects;
5. Numbers of and reason for withdrawal of subjects from the research;
6. A summary of any relevant information about risks associated with the research;
7. Number and demographics of participants enrolled;
8. Changes in the principal and / or associate investigator(s);
9. A summary description of subject experiences;
10. Research results obtained thus far;
11. A current risk-benefit assessment based on the study results, and
12. Any new information since the IRB's last review.

Section 16.02 Continuing Review Procedures

After it is established that a continuing protocol submission is completed by the Secretary and the Coordinator, it shall be submitted to the IRB and reviewed by the convened IRB or Expedited Reviewer(s), if necessary for an Expedited Review.

Article XVII. ADMENTMENT REQUEST

Amendment applies to change(s) made to a previously submitted IRB-approved research protocol but is later amended by an investigator and re-submitted for approval by the IRB prior to its implementation.

Section 17.01Amendment Submission Requirements

1. Letter of request.
2. Completed Amendments to Approved Study form.
3. A revised Application Narrative that documents the modified protocol, using tracked changes.
4. A copy of all altered study materials using tracked changes (that includes recruitment materials, consent forms, data collection forms, etc.).

Section 17.02 Amendment Review Process

The Secretariat shall review and forward the completed protocol submissions to the IRB for review.

The protocol submission is reviewed either via expedited procedures (for minor changes) or via full IRB review (for all other changes). The criteria for approval are the same as for initial review (See Section 9.03).

Section 17.03 Changes Not Requiring Review

(a) Study Procedures

1. Rescheduling of a data collection as a result of research subject missing an appointment or incomplete data collection due to unforeseen circumstances that do not increase risk to the subjects.
2. Rescheduling of specimen collections as a result of a research subject missing an appointment or incomplete specimen collection due to unforeseen circumstances that do not increase risks to the subject. Specimen collections that qualify for this category are as follows:
    a. Collection of blood via finger, or ear stick;
    b. Hair and nail clippings collected in a non-disfiguring manner; excreta and external secretions (including sweat);
    c. Sputum collected through expectoration, etc.
3. Removal of study instrument(s) as long as such removal do not reduce any previously established direct benefit to participants or reduce the validity of the study.
4. Minor editorial changes to study instruments (e.g., corrections of grammar/language to increase participant understanding).

Section 17.04 Recruitment Materials

1. Changes within the approved recruitment material (e.g., changes across presentation platform, for example, flyer to newspaper advertisement).
2. Changes in contact information. However, the addition of new Investigator or other key personnel to the study is substantive, hence, requires IRB review and approval.
3. Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).
4. Updating dates and times related to when research activities will occur (so long as such dates/times and number of data collection activities are within the approved protocol period and do not increase the duration of a subject's participation).

Section 17.05 Consent/Assent Documents

1. Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).
2. Changes in contact information except where new Investigator or other key personnel is added to the study. The addition of new Investigator or other key personnel is a substantive change to the study and must be submitted to the IRB for review and approval.
3. Changes noting removal of a study instrument and resulting change of duration of participation. Changes adding study measures are substantive and must be submitted as an amendment for IRB review and approval.

Article XVIII. POST-APPROVAL MONITORING

Section 18.01 Protocol Selection

1. A protocol may be selected to undergo post-approval monitoring due to the following reasons: Due to reported complaints and/or requests by the convened IRB.
2. From continuing review or reports from other sources, it is revealed that material changes may have occurred without IRB approval.
3. Where an Investigator conducting a project has previous records of noncompliance.
4. Projects involving vulnerable populations that raise cause for concern.
   Complex projects involving unusual levels or types of risks to subjects.
5. Upon request by the Investigator.
6. In response to inquiries from external regulatory agencies.

Section 18.02 Monitoring Procedures

When a protocol is selected, the person responsible to conduct the monitoring shall inform the Investigator that his/her protocol has been selected for monitoring followed by a second contact within five business days of the first, to schedule the visit. During the visitation, the Monitor will meet and interact with the Investigator and the research team on the research procedures, and prepare and provide a draft report to the Investigator within 15 business days.

The Investigator must respond to the draft report in 15 business days and advice of changes, otherwise, the report will be considered accurate and finalized. However, if due to some challenges that the Investigator cannot respond within this time frame, he/she can request an extension.

Section 18.03 Reporting of Monitoring Results

The Monitor will submit the final report to the IRB Chair who may request revisions to the research protocol by the Investigator based on the information and recommendations provided by the Monitor. If the monitoring reveals serious or continuing noncompliance, the matter will be handled in accordance with the procedures outlined in Article XVI: Noncompliance.

Article XIX. INFORMED CONSENT REQUIREMENTS

Section 19.01 Required Elements of Informed Consent

1. Statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
5. A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained.

6. A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
7. For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of research-related injury to research subjects.
9. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which a research subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
   For research that involves the collection of identifiable private information or identifiable bio-specimens, one of the following must be included in the informed consent:
   a. A statement that identifiers will be removed from the identifiable private information or identifiable bio-specimens and that, after such removal, the information or bio-specimens could be used for future research studies without additional informed consent from the subject or the LAR; or
   b. A statement that the subject's information or bio-specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Section 19.02 Review of Informed Consent Processes and Documents

If the informed consent procedures and consent document(s) are reviewed by the Secretariat to be complete, it is submitted to the IRB for review and if it qualifies for expedited review, it will be conducted by the IRB Chair, or designated expedited reviewer. After the Investigator make the required changes as suggested by the IRB, the application could be approved by the Chair.

Article XX. WAIVER OR ALTERATION OF INFORMED CONSENT

To obtain a waiver or alternation of informed consent, the Investigator must include the request (and provide justification for the waiver or alternation) in the protocol submission process. The request for waiver or alteration will be reviewed by the convened IRB, or by the IRB Chair or designated expedited reviewer. The IRB reviewer (Chair or designee) may approve the waiver or alteration of informed consent, if the IRB reviewer can establish that:

1. The research is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   a. Public benefit or service programs;
   b. Procedures for obtaining benefits or services under those programs;
   c. Possible changes in or alternatives to those programs or procedures; or
   d. Possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

Section 20.01 Approval of waiver

The IRB reviewer (Chair, or designee) may approve the waiver or alteration of informed consent, if the IRB reviewer determines:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be conducted without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or LAR will be provided with additional pertinent information after participation.

The IRB reviewer will document the findings for Waiver or Alteration of Informed Consent. An alteration to informed consent may apply when conducting a study where there is deception or an incomplete disclosure (for example, studies that require deception because the study would be compromised if participants were told the true purpose).

Section 20.02 Waiver of Signed Consent Form

A waiver of a signed informed consent form may be appropriate for some research studies such as survey or interview studies containing highly sensitive questions (e.g., health status, sexual practices, criminal behavior, etc.), or surveys containing non-sensitive information.

To obtain a waiver of documented (signed) informed consent, the Investigator must include the request (and provide justification for the waiver or alternation) in the protocol submission process. The request for waiver or alteration will be reviewed by the convened IRB or by the IRB Chair or designated expedited reviewer.

The IRB reviewer will consider the Investigator's request and review the request to determine either:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research, such as an information sheet, instead of an informed consent document.

Article XXI. NONCOMPLIANCE

Noncompliance is when Investigators fail to comply with IRB, national, or international guidelines for the conduct of human subject research, or when an Investigator fails to respond to IRB requests or queries.

Section 21.01 Handling Reports of Noncompliance

The IRB is charged with the authority to receive, investigate and make determinations about complaints, allegations, and/or incidents of noncompliance associated with all Human Subjects Research, both IRB-approved protocols and concealed activities (that should have been submitted to the IRB for review), and take action to protect human subjects and promote compliance.

Reports, complaints or allegations of noncompliance should be made to the Secretariat within 48 hours after the Investigator first learned of the event. Initial reports can be made either orally or in writing, with a written follow up thereafter. Upon receipt of the reports, complaints, or allegations of noncompliance, the Coordinator should immediately report it to the IRB Chair, or designee.

The IRB Secretariat or IRB designee, will compile the information regarding the allegation, complaint or report and submit the information to the IRB for further review and processing as needed.

Article XXII. UNANTICIPATED PROBLEM AND ADVERSE EVENT REPORT

An adverse event is any unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research. Adverse events encompass both physical and psychological harms. Any adverse event is considered a Serious Adverse Event when it:

1. Results in deaths;
2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. Results in inpatient hospitalization or prolonged hospitalization;
4. Results in a persistent or significant disability/incapacity;
5. Results in a congenital anomaly/birth defect; or
6. Based upon appropriate medical judgment, may jeopardize the subject's health, and may require medical or surgical intervention (e.g., the development of drug dependency or drug abuse, etc.).

Section 22.01 Identifying Unanticipated Problems

The Investigator must promptly report any Unanticipated Problems to the IRB in accordance with the following guidelines:

1. Unanticipated problems that are Serious Adverse Events must be reported to the IRB within five (5) business days of the Investigator becoming aware of the event. The IRB strongly recommends that a preliminary report be submitted by the researcher within 48 hours of learning of the Serious Adverse Event with a formal follow-up report submitted within the above timeline.

2. Any other unanticipated problem should be reported to the IRB within two (2) weeks of the Investigator becoming aware of the problem. The IRB strongly recommends that a preliminary report be submitted by the researcher within five (5) business days of learning of the Unanticipated Problem with a formal follow-up report submitted within the above timeline.

Section 22.02 Reporting Unanticipated Problems

When making a report to the IRB, an Investigator should include the following information:

1. Appropriate identifying information for the research protocol, such as the title, Investigator's name, and the IRB project number;
2. A detailed description of the Adverse Event, incident, experience, or outcome; however, to maintain confidentiality, subjects' names and identifiable information should not be included in the report;
3. An explanation of the basis for determining that the Adverse Event, incident, experience, or outcome represents an unanticipated problem; and
4. A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

Section 22.03 IRB Review and Response

Initial review of Unanticipated Problems will be conducted by the IRB Executive Committee. The IRB Executive Committee is authorized to take the following actions in response to any incident report:

1. Conduct an administrative review of the report, including assessing whether the incident constitutes an Unanticipated Problem.
2. If a convened IRB review is needed, the IRB Chair assigns the incident report for review at the next available regularly scheduled IRB meeting.
3. Alternately, the IRB Executive Committee may convene an emergency meeting of the IRB to review the report.
4. If the IRB Executive Committee finds that the rights, safety, and welfare of subjects are jeopardized by the research, the Chair may suspend the research until at such time when the full IRB can convene to review the report.

When reviewing a particular incident, experience, or outcome reported as an Unanticipated Problem by the Investigator, the IRB may determine that the incident, experience, or outcome does not meet the criteria for an Unanticipated Problem.

Section 22.04 Possible actions after review of unanticipated problems

After reviewing the Unanticipated Problem report, the IRB may require the following actions, in order to protect the ongoing safety of research subjects:

1. Modification of subject inclusion or exclusion criteria to mitigate the newly identified risks;
2. Implementation of additional procedures for monitoring subjects;
3. Modification of informed consent documents to include a description of newly recognized risks;

4. Provision of additional information about newly recognized risks to previously enrolled subjects;
5. Suspension of enrollment of new subjects;
6. Suspension of research procedures in currently enrolled subjects;
7. Suspension of the entire study; or
8. Termination of approval for the entire study.

If the solution to an Unanticipated Problem is to amend the research protocol and/or informed consent forms, then, an amendment request must be made to the IRB. If the changes are minor, they may be reviewed by expedited review procedures. If the changes are major, they must be reviewed and approved by the convened IRB. Changes made in response to an Unanticipated Problem must be reviewed and approved by the IRB before being implemented, except where implementation is necessary to eliminate immediate hazards to research subjects.

Article XXIII. SUSPENSION OR TERMINATION OF RESEARCH

Suspension is the temporary cessation of some or all activities in a currently approved research study; Termination is a determination made by the IRB to permanently withdraw approval for some or all activities of a currently approved research study. A research study may be suspended or terminated for a variety of reasons, including but not limited to:

1) Failure to obtain appropriate consent or keep appropriate study-related paperwork;
2) Conduct of research activities without prior IRB approval;
3) Serious adverse event(s);
4) Detrimental change in the risk-benefit ratio of the study;
5) Failure of investigators to complete required training, etc.

Section 23.01 Authority

The convened IRB is authorized to suspend or terminate approval of research protocols that are not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. The IRB Chair, or his/her designee, is authorized to suspend research protocols in emergency situations, such as when the rights, safety, or welfare of research subjects are at immediate risk.

Section 23.02 Process and Notification for Suspension or Termination

The IRB will review the circumstances of the case and determine whether a research study should be suspended or terminated. The IRB Secretariat will be consulted as needed in the decision-making process.

In the case of emergency, or severe noncompliance that puts the rights, safety, or welfare of human subjects at immediate risk, the IRB Chair, or his/her designee may suspend a study in consultation with the ACRE Board of Directors A suspended research study shall be scheduled for the next convened IRB regularly scheduled meeting to determine whether the suspension should continue or be lifted, reinstating active approval, or terminating the research protocol.

Following the suspension/termination action of the IRB, the Chair will inform through writing, the Investigator, any sponsor(s), and any other individuals or entities deemed appropriate, that includes the following:

1) A description of the event,
2) The determination of the IRB (i.e., suspension, termination),
3) Justification for the determination, and
4) Requirements of the investigator (e.g., cease all data collection).

The IRB reserved the right to inform other ethics review bodies about a study that have been suspended or terminated.

Section 23.03 Consideration for termination

The following should be considered by the IRB when suspending or terminating a research protocol:

1) Whether the suspension or termination protects the rights and welfare of participants;
2) Whether withdrawal procedures of enrolled research subjects take into account their rights and welfare (e.g., continuation of medical care after cessation of the research study);
3) Whether to inform current participants of the suspension or termination;
4) Whether to require participant follow-up for safety concerns; and
5) Whether to inform current participants of reported matters (unanticipated problem, adverse events, noncompliance, etc.).

Section 23.04 Consequences of Suspension or Termination

Suspending or terminating a protocol means that the Investigator must stop all research activities on the protocol, including recruiting and enrolling participants, treatment, and analysis and/or publication of existing data. If any data was collected between the date of the termination notice and receipt of the termination notice, the Investigator must discard that data. Additionally, data that were collected during the study approval period may no longer be used since approval for the study has been terminated. When the suspension or termination of a research protocol involves the withdrawal of current participants from the research, the Investigator will be required to:

1) Inform enrolled participants that the study has been suspended or terminated; and
2) Develop procedures for withdrawal that protect the rights, safety, and welfare of participants, and describe those procedures to participants.

Section 23.05 Continuing a study despite reason to suspend or terminate

Under certain conditions, the project activities may continue if stopping study procedures or treatment would adversely affect the welfare of the subject(s). When the suspension or termination of a research protocol does not involve the withdrawal of current participants from the research, the Investigator will be required to:

1) Notify the IRB office immediately of the need to continue any procedures/treatment;
2) Inform enrolled participants that the study has been suspended or terminated; and
3) Report any adverse events or unanticipated problems involving risks to participants.

Section 23.06 Reinstatement of Protocols

The IRB shall reinstate a suspended research study once the Investigator has satisfactorily resolved all pending issues raised by the IRB. If after six months the Investigator has not made adequate progress on the pending issues, the IRB will close the study. The Investigator must contact the IRB Chair in writing within thirty (30) days of the suspension, addressing the following issues:

1) Reason for requesting the study to be reinstated.
2) Short summary of the purposed study and intended objectives/outcomes.
3) Description of how the study has changed, if any, since initial approval.
4) Summary status of the study, including:
    a) How many subjects were enrolled?
    b) At what point in the treatment/procedures were the subjects enrolled?
    c) Any adverse events or amendments since the last continuing review, including a description of each?
    d) Any additional relevant information?
5) Documented plan to ensure that the reason for the suspension will not happen again and that the study will be in compliance with all applicable laws and regulations, and
6) Anticipated enrollment, if the study is reactivated.

In the case that IRB approval of a protocol is reinstated, the IRB may require that subjects who were previously enrolled be re-consented. Terminated research studies cannot be reinstated. Instead, Investigators must submit a new research study application.

Article XXIV. RESEARCH INVOLVING VULNERABLE POPULATIONS

Section 24.01Research Involving Pregnant women and fetuses

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2) The risk to the fetus is caused solely by the interventions or procedures considered directly beneficial for the woman or the fetus; or, if there is no such prospect of specific benefit, the risk to the fetus is not greater than minimal and the purpose of the research is for the development of important biomedical knowledge which cannot be obtained by any other means;
3) Any risk is the least possible for achieving the objectives of the research;
4) If the research holds out the prospect of direct benefit to pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent is obtained in accordance with the informed consent provisions (Section 15.0: Informed Consent Requirements);
5) If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accordance with the informed consent provisions (Article XIV: Informed Consent Requirements), except that the father's consent need not be

obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest (close relationship).

6) Each person providing consent is fully informed regarding the foreseeable impact of the research on the fetus and/or resultant child;
7) For children who are pregnant, assent and permission are obtained in accordance with the provisions for children (Section 21.0: Research Involving Children);
8) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10) Individuals engaged in the research will have no part in determining the viability of a fetus.

Section 24.02 Research Involving Children

The IRB must classify research involving children into one of four categories and document its discussion of the risks and benefits of the research study in order to approve such research. These categories are:

1) When the IRB determines that the risk is no more than minimal to children in a study, it may approve the research only if adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians (45 CFR 46.404).
2) When the IRB determines that more than minimal risk to children is presented by a procedure that indicates the prospect of direct benefit to an individual child, or by a monitoring procedure that is likely to contribute to the child's well-being (45 CFR 46.405), the IRB may approve the research if it is established that:
   a) The risk is justified by the anticipated benefit to the children;
   b) The relation of the anticipated benefit to the risk is at least as favorable to the children as that presented by available alternative approaches; and
   c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians.
3) When the IRB determines that the study presents more than minimal risk to children but does not hold out the prospect of direct benefit for the individual child but is likely to contribute generalizable knowledge about the child's disorder or condition (45 CFR 46.406), the IRB may approve the research if it established that:
   a) The risk represents a minor increase over minimal risk;
   b) The study intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
   c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or improvement of the subjects' disorder or condition; and
   d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians.
4) When the IRB determines that the research does not meet the requirements in any of the above three categories, the IRB may only approve the research if it finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children (45 CFR 46.407).

(a) Adequate Provisions for Assent of Children

(i) Children capable of assenting

After the IRB determines that a child is capable of assenting, the proposed research procedures should be explained to him/her in language that is appropriate to his/her age, experience, maturity, and condition and should include any discomforts and inconveniences the child may experience if he/she agrees to participate in the study.

(ii) Option to withdraw

As they are in the developmental stage, children should be asked if or not they wish to participate in the research, especially where the research does not involve interventions likely to be of benefit to the subjects but that they will be volunteers for the benefit of others.

(iii) Signing assent or consent

When an assent requirement is established, the investigator or his/her designee and the child (when appropriate) will sign the study consent form. When it is inappropriate for the signature of the child (due to age or ability), the IRB requires that the document be signed by the investigator (or his/her designee) and the parent(s)/LAR(s).

(b) 21.3 Waiver of Assent

The IRB may determine that assent is not necessary if:

1) The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
2) The intervention or procedure involved in the research has a direct benefit to the health or well-being of the children and is available only in the context of the research. In such instances, a child's dissent which should normally be respected, may be overruled by his/her parents at the discretion of the IRB (For example, when research involves providing experimental therapies for life-threatening diseases such as Ebola Virus Disease, Severe COVID -19, cancer, parents may wish to try anything to help their children, even with the likelihood of success being uncertain). If the child is a matured adolescent, his/her wishes should be respected.

(c) Permission of Parents or Legal Guardians

The IRB should ensure that adequate provisions are made for soliciting the permission of each child's parents, guardian or LAR. The following provisions are used depending on the category of the research:

1) Research not involving greater than minimal risk to children: Where parental permission is to be obtained, the IRB may suggest that the permission of one parent is sufficient for research not involving greater than minimal risk.
2) Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child: Where parental permission is to be obtained, the IRB may suggest that the permission of one parent is sufficient for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
3) Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition: When the research is approved under this category, both parents must give their permission unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children: When the research is approved under this category, both parents must give their permission unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(d) Waiver of Parental or Legal Guardian Permission.

If it is determined by the IRB that a research study is designed for a subject population for which parental, or guardian or LAR permission is not reasonably required to protect the subjects (e.g., neglected or abused children), the consent requirements may be waived. The IRB, in order to protect the rights and welfare of children in a research, should consider the involvement of a court appointed guardian.

Section 24.03 Research Involving Prisoners

Due to the vulnerability of prisoners, research involving prisoners should be reviewed by the full convened IRB. An IRB may only approve research projects involving prisoners if the research falls under one of the following categories:

1) Study of possible causes, effects and processes of incarceration, and of criminal behavior, provided that the study present no more than minimal risk or inconvenience to subjects;
2) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
3) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on Ebola, COVID -19, hepatitis, as well as social and psychological research such as alcoholism, drug addiction, and sexual assaults); or
4) Research on practices that are intended and have the probability of improving the health or well-being of the subjects.

Section 24.04 Consideration for research involving prisoners

The IRB shall review research involving prisoners and approve such research only if it finds that:

1) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
2) Procedures for the selection of subjects within the prison are fair to all prisoners and free of arbitrary interference by prison authorities or prisoners. Except the Investigator justifies to the IRB, the use of other procedures, the selection of control subjects from available prisoner population for a particular research study should be randomly done;
3) The information is presented in language which is understandable to the subject population;
4) There is adequate assurance that parole boards will not take into account a prisoner's participation, withdrawal or lack of participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that their participation, withdrawal or lack of participation in the research will have no effect on his or her parole; and
5) The IRB should ensure that adequate provisions are made where there will be a follow-up examination or care of subjects after the end of their participation, considering the variable lengths of individual prisoners' sentences, and informing subjects of this.

Article XXV. Annexes

Section 25.01 Review Fees Charge

ACRE IRB Review Fees Chart

No.	Study Description	Amount (USD)
1.	Health, Behavioral and Education Research	$500.00
2.	Clinical Trial	$5,000.00
3.	Re-Submission	$500.00
4.	Continuing Review	$500.00
5.	Amendment (Six months or less after approval)	FREE
5a.	Amendment (More than six months after approval)	$500.00
6.	Foreign Student	$375.00
7.	Liberian Student	$250.00

Section 25.02 Initial Review Template

ACRE IRB Submission Form

Name of Project *(Use title submitted to funding source)*		
Protocol Title		
Principal Investigators (PIs)		E-Mail: Phone:
Affiliation		
Address		
Name of person presenting to IRB, if other than PI		E-Mail: Phone:
Date of Submission		
Project Code #		Grant #:

Funding Type	Grant ☐ Contract ☐ Subcontract ☐ ☐ Other: Pilot study to obtain data for a proposed future R01 grant application	Funding Agency:

Is there an IRB Authorization Agreement in place for this project? ☐ Yes ☐ No

If yes, indicate name of organization:

Type of Review Requested	Initial	☐ Full Submission—all planned research activities are being presented for review ☐ Partial Submission—only some research activities are being presented for review at this time
	Exemption	☐ Exemption of full study is being requested
	Regular Renewal	☐ All research activities are being reviewed (typically annually)
	Interim Modification	Only some research activities are being reviewed at this time (i.e. a modification is being made to something already approved or a new component is being added)

	Final	☐ Study has ended (no more subject enrollment, no intervention, no data collection, and remaining data are either de-identified or maintained with safeguards)

Does this submission request a waiver of informed consent? ☐ Yes ☐ No

☐ Check here if a waiver of informed consent was granted in an earlier submission

Does this protocol involve a clinical trial? *(A prospective study to test the effect of a biomedical or behavioral intervention in human subjects.)* ☐ Yes ☐ No

If yes, what phase? ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

Has the funding Institute required a DSM plan? ☐ Yes ☐ No

If yes, is a Data and Safety Monitoring Plan attached? ☐ Yes ☐ No

1. Summary—*Give a <u>brief</u> summary (such as the proposal abstract) of the nature of the proposed research and summary of data collection activities. If this project is a collaborative, please indicate collaborators and clarify their role in the project.*

2. Review of Project Activities since Last Regular Renewal Review*—Do NOT complete this section if this is an INITIAL submission. Include the following (for multi-component projects, describe each component separately): a brief description of project activities to date, the number of subjects enrolled, relevant information regarding risks associated with the research, and description of Interim Modification Reviews since the last Regular Renewal Review.*

3. Proposed Changes in Human Subjects Protocols—*Do NOT complete this section if this is an INITIAL submission. Describe any changes and complete Sections 5-9 if new components are being added. If current instruments or consent forms are being revised, attach them with changes clearly indicated.*

4. Description of Any Incidents Involving Human Subjects—*Do NOT complete this section if this is an INITIAL submission. Provide a summary of: any human subjects incidents and/or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, and complaints about the research since the last IRB review. Alternately, indicate if no incidents have occurred.*

5. Subjects—*Complete this section for INITIAL submissions and as needed for other submissions. Describe the proposed human subjects including: the number to be recruited and their characteristics, how they will be contacted and selected for participation, the local research context, and whether any proposed subjects are members of a vulnerable population (i.e. fetuses, pregnant women, human in vitro fertilization, prisoners, or children).*

Subjects:

Local (In-country) Research Context.

6. Procedures—*Complete this section for INITIAL submissions and as needed for other submissions. Explain how human subjects will be involved, exactly what will be expected of them, the procedures for obtaining informed consent, and how data will be collected and maintained. If requesting a waiver concerning informed consent, complete Section 11.*

Survey

Data Collection Methodology

Data Analysis

7. Risks—*Complete this section for INITIAL submissions and as needed for other submissions. Describe foreseeable physical, psychological, or social risks or discomforts to the subjects.*

Potential Risks.

8. Safeguards—*Complete this section for INITIAL submissions and as needed for other submissions. Explain procedures to be used to minimize each of the potential risks listed in Section 7. Describe procedures for: protecting the participants' privacy; maintaining confidentiality of the data; and monitoring staff compliance to IRB-approved protocol.*

9. Benefits—*Complete this section for INITIAL submissions and as needed for other submissions. Describe benefits to be derived from the proposed research for the human subjects and/or for society.*

10. Request for Exemption—*Refer to 45 CFR 46.101 (b) and indicate the paragraph citation (1-6) that applies to either the full project or specific component(s). Provide specific justification based on project design. Include appendix materials (surveys, interview protocols, focus group guides, recruitment flyers, etc.) related to this study.*

☐ Exemption of Full Project—45 CFR 46.101 (b)(_____)

☐ Exemption of only some project component(s). *List components for which exemptions are being requested, providing exemption citation for each component.*

11. **Request for Consent Waiver**— *If a waiver of consent is requested, document the appropriate requirements:*

☐ Waiver of Informed Consent—45 CFR 46.116(d)—*address 1 through 4*

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

☐ Waiver of ***Documentation*** of Informed Consent—45 CFR 46.117(c)—*address 1 or 2*

(1) the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

12. Disposition of Project—*Complete this section for Final IRB Review only. For IRB purposes, the project has ended when there is no more subject enrollment, no intervention, no data collection, and remaining data are either de-identified or maintained with safeguards. Describe here the disposition of the project and its data and provide a brief summary of findings.*

13. List of Attachments—*Provide a <u>numbered</u> list of documents attached to this submission (i.e. questionnaires, surveys, interview schedules, recruitment and interview scripts, and recruitment materials). Include the attachment number as part of the electronic file name and on each document.* ***For Initial Review, OHRP requires that the original proposal (Face Sheet, Abstract, and Research Section including the Human Subjects Section) is included for review. Please attach as an appendix****. For Regular Renewal or Interim Modification Reviews, attach current consent document(s) and include instruments ONLY if changes are being proposed.*

Appendix 1: Letter of Application

Appendix 2: Copy of Proposal

Appendix 3: Informed Consent and/or Assent Form

Appendix 4: Sample Questions Survey.

Appendix 5: CVs of Investigators

Appendix 6: Protocol budget

Appendix 7: Copy of IRB Approval from an Institutional Review Board (IRB), if available

Section 25.03 Informed Consent Form

Study Title:

Principal Investigator:

Student Researcher: [if applicable]

I am a [profession] at the [Institution]. I am [We are] planning to conduct a research study, which I invite you to take part in. I am doing this study with colleagues at [name other institutions, if this is a multi-institutional study.] This form has important information about the reason for doing this study, what we will ask you to do if you decide to be in this study, and the way we would like to use information about you if you choose to be in the study.

Why are you doing this study? (Purpose)
You are being asked to participate in a research study about ….
The purpose of the study is …

[Note: If the study involves deception or incomplete disclosure that necessitates a debriefing process, a general statement may be added here that more information will be given to subjects at the conclusion of the study, e.g., "At the end of the study, we will explain in greater detail what we hope to learn from this research." If the investigator believes that such a statement would bias study results, he/she should discuss this in the protocol as part of the justification for use of deception or incomplete disclosure.]

What will I do if I choose to be in this study? (Procedure)
You will be asked to [explain what the participant will be asked to do].

- Provide a clear, concise but complete description of what subjects will do or experience.
- Describe activities in chronological order to the extent possible.
- If there are many procedures, use a table, lists, or subheadings to organize this information.

Study time: Study participation will take approximately [insert expected length of time--include the total time commitment, the number of visits/sessions involved, and the length of each visit/session].

Study location: All study procedures will take place at [explain study location(s) -- if different procedures will take place at different locations, specify accordingly].

[If you will be audio-recording or video-recording subjects, include the following]
I would like to audio-record [or video-record] this interview to make sure that I remember accurately all the information you provide. I will keep these tapes in [explain where you will keep them] and they will only be used by [explain who will have access to the tapes]. If you prefer not to be audio-recorded, I will take notes instead. [If audio/video recording are not optional, then clearly state that it is required for participation.]

[If you plan to quote statements made by participants, including the following]
I may quote your remarks in presentations or articles resulting from this work. A pseudonym will be used to protect your identity, unless you specifically request that you be identified by your true name.

What are the possible risks or discomforts?

Explain any foreseeable risks to subjects here. Keep in mind that risks are not always immediate -- anger, emotional upset, or stress may appear later.

Examples:

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

OR

Your participation in this study does not involve any physical or emotional risk to you beyond that of everyday life.

OR

Your participation in this study may involve the following risks… [Describe any reasonably foreseeable risks to psyche, reputation, employability, insurability, social status, criminal or civil liability that may occur as a result of your participation.]

Address emotional and psychological risks, including risks of emotional discomfort from being asked about or discussing sensitive issues.

Examples:

- You may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you wish to take a break or stop the interview.
- You may be uncomfortable with some of the questions and topics we will ask about. If you are uncomfortable, you are free to not answer or to skip to the next question.

As with all research, there is a chance that confidentiality of the information we collect from you could be breached – we will take steps to minimize this risk, as discussed in more detail below in this form.

What are the possible benefits for me or others?

You are not likely to have any direct benefit from being in this research study. This study is designed to learn more about [insert purpose/topic of study]. The study results may be used to help other people in the future.

OR

Taking part in this research study may not benefit you personally, but we may learn new things that will help others.

OR

The possible benefits to you from this study include…

[Do NOT include information on payment/reimbursement in the description of benefits – that information belongs in a separate Financial Information section.]

How will you protect the information you collect about me, and how will that information be shared? (Confidentiality & Privacy)

Results of this study may be used in publications and presentations. Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used [if appropriate, add phrase such as "unless you give explicit permission for this below"].

To minimize the risks to confidentiality, we will... [Explain data security measures to be taken, e.g., storage, coding, encryption, limited access to study records, etc. If disclosure of faces or voices is necessary to understanding the research and therefore identifying information may be used in reports/presentations, explain this and provide "I agree" "I do not agree" options at the end of the consent form.]

We may share the data we collect from you for use in future research studies or with other researchers – if we share the data that we collect about you, we will remove any information that could identify you before we share it. (tweak this data sharing language as needed to fit your study – for example, if you might share data that potentially could be identifiable, such as videotapes, then you should make that clear).

If we think that you intend to harm yourself or others, we will notify the appropriate people with this information.

Financial Information

Participation in this study will involve no cost to you. You will not be paid for participating in this study.
OR
[If subjects will be paid, explain the amount and terms of payment/reimbursement. If payments will be prorated if a subject withdraws from the study, explain the conditions for payment]

What are my rights as a research participant? (Voluntarism)

Participation in this study is voluntary. You do not have to answer any question you do not want to answer. If at any time and for any reason, you would prefer not to participate in this study, please feel free not to. If at any time you would like to stop participating, please tell me. We can take a break, stop and continue at a later date, or stop altogether. You may withdraw from this study at any time, and you will not be penalized, neither denied due benefits in any way for deciding to stop participation.
If you decide to withdraw from this study, the researchers will ask you if the information already collected from you can be used [or in the alternative, state that any information collected from the participant will not be used if the participant decides to withdraw before finishing the study.]

Who can I contact if I have questions or concerns about this research study?

If you have questions, you are free to ask them now. If you have questions later, you may contact the researchers at [add your contact information, including name, telephone number, and email address].

If you have any questions about your rights as a participant in this research, you can contact the following persons:

Mr. Edward G. Smith
Chairperson
ACRE IRB
Graduate School Building
University of Liberia Capitol Hill Campus
Monrovia, Liberia
Phone: (088) 654-7343 | (077) 754-7343
Email: smithedwardg@yahoo.com

Mr. Jemee K. Tegli
Coordinator
ACRE IRB
Graduate School Building
University of Liberia Capitol Hill Campus
Monrovia, Liberia
Phone: (088) 658-3774 | (077) 758-3774
Phone: jktegli@yahoo.com

Consent

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been adequately answered. If I have additional questions, I have been told whom to contact. I agree to participate in the research study described above and will receive a copy of this consent form.

_____ _____

Participant's Name (printed) Date

_____ _____

Participant's Signature Date

_____ _____

Person Obtaining Consent Date

Section 25.04 Protocol Amendment Form

ACRE INSTITUTIONAL REVIEW BOARD
PROTOCOL AMENDMENT FORM
Submitting Changes to Previously Approved Human Subjects Research

All applications must be completed, signed by the RPI and submitted to

All modifications to human subjects' research must be reviewed and approved prior to implementation.

Minor modifications Minor modifications to previously approved projects include those that do not alter the risk–benefit assessment for the research. Examples include changes in the investigators; minor changes in the consent form(s), recruiting materials, measures, or procedures; minor changes in compensation, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol.

Major modifications Major modifications include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); or that involve a decreased benefit; or that otherwise result in alteration of the risk–benefit assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications.

1. **DATE THIS REPORT WAS COMPLETED:** _____
   AMENDMENT NUMBER (START WITH 01): _____

2. **RESPONSIBLE PROJECT INVESTIGATOR (RPI)**

Last Name:	First Name:	Academic Degree(s):
Affiliation:		Mail Code:
St Address:	City:	State:
Phone:	Fax:	E-mail:

3. PROJECT TITLE **IRB PROTOCOL NUMBER:** ☐

☐

4. MAJOR OR MINOR MODIFICATION? In the RPI's judgment, which category of modification is this?

☐ Minor ☐ Major ☐ Uncertain

5. REVISED MATERIALS: For revisions to currently approved procedures (including discontinuation of previously approved procedures, measures, etc.), or to add new procedures that were not previously approved, please resubmit the New Protocol Application Form or Application for Exemption incorporating the revisions as appropriate throughout the form. Amendments often require modification of consent forms, assent forms, measures and other relevant attachments.

PLEASE SUPPLY THE FOLLOWING with this Research Amendment:

a) A marked up version of the New Protocol Application or Application for Exemption and any modified attachments or consent documents. NOTE: If your computer does not allow "strike-through" or other editing on the New Protocol Application or Application for Exemption, it is acceptable to cross off deleted sections with a pen and use a highlighter to emphasize changes.
b) The **entire** New Protocol Application or Application for Exemption reflecting the revisions.
c) Revised consent documents and other relevant attachments that have changed as a result of the amendment

→ Mark One: Changes marked versions and final versions are: ☐ Attached ☐ Will Follow.

6. DESCRIBE THE AMENDMENT. Describe the requested change(s) and clearly reference materials submitted with this form. Provide a clear rationale for the proposed change(s). Explain whether the risk–benefit assessment for the research is likely to change as a result of the proposed amendment(s). Justify changes that will affect risks, benefits, informed consent, inclusion or exclusion criteria, the subject population(s), research sites, or the confidentiality of private, identifiable subject information.

If additional Item 6 information is attached, check here: ☐

7. INVESTIGATOR ASSURANCES The original, inked signature of the Responsible Project Investigator is required before this form can be processed. Other investigators are also responsible for these assurances and are encouraged to sign. Neither stamps nor proxy signatures are accepted in this section.

I certify that the information supplied in this form, with attachments, is complete and correct, that the modified protocol has not yet been used with any human subject, and that it will not be implemented until IRB approval has been obtained.

NOTE: The signature of the RPI must be submitted before IRB Review (scanned or faxed signatures are acceptable).

Responsible Principal investigator	Date	Investigator	Date
Investigator	Date	Investigator	Date

Protocol # _____

Re-Approval____Completion ____

ACRE IRB Continuing Review Submission Form

This form must be submitted at the time of continuing review or study completion.
All questions relate to the last approval period.

I. General Information

Name of Project *(Use title submitted to funding source)*		
Principal Investigators (PIs)		E-Mail: Phone:
Affiliation		
Address		
Name of person presenting to IRB, if other than PI		E-Mail: Phone:
Date of Submission		
PIRE Project Code #		Grant #:
Funding Type	☐ Grant ☐ Contract ☐ Subcontract ☐ Other: Pilot study to obtain data for a proposed future R01 grant application	Funding Agency:

Is there an IRB Authorization Agreement in place for this project? ☐ Yes ☐ No

If yes, indicate name of organization:

II. Status of Study:

In the first column, check **ONE** of the following...	
	On-Going. If so, …
	Are participants still being enrolled in the study?_____**Yes**_____**No**
	Have all enrolled participants completed all study interventions?____**Yes**_____**No**
	Is the research active only for long-term follow-up of enrolled participants?____**Yes**_____**No**
	Data Analysis. *A study is considered to be in "Data Analysis" if data is being analyzed, and/or maintained for purposes of publication (i.e., a manuscript has been submitted but the publisher may ask for revisions that would require re-analysis of data).* **Status**: _____
	Completed. *A study is considered to be "Completed" if data analysis is done, and there is no additional research beyond the original intent planned for this data. Use of this data for other research purposes requires submission of a new protocol application.* **Date of Completion**: _____
	Since the last IRB approval (continuing or initial), have there been any changes in the personnel working on the study?_____Yes ___No **If Yes, submit a revised listing of old and new personnel/Research Assistants.**

III. Study Summary and Progress Report

Findings

Describe the current status of the research (e.g., phase 1 completed, phase 2 scheduled to start in two months); provide a summary of findings/analysis conducted during the approval period; state whether the findings are consistent with what you expected; and provide a brief description of the plans for the study during the upcoming approval period. IMPORTANT - Please note that it is not acceptable to simply copy last year's findings section. The IRB must review the activity that occurred within the last approval period. If no work was conducted on this study during the last approval period, please state so and explain why (e.g., too busy with other projects, delay in funding, unable to hire a graduate student to work on the project, etc.). If closing the study, please attach a copy of any publications or manuscripts resulting from the study.

Are there any new findings that may impact a participant's willingness to continue this study? Indicate "Yes" or "No." If yes, please describe the findings, and explain how these findings have been communicated to participants.

If applicable, provide a summary of the findings of the data safety monitoring plans/board meetings and the date of the last DSMB meeting.

Literature *Provide a summary of the recent literature by other authors that provides new information bearing on this study's risk/benefit analysis, and attach copies of such articles to this form. If a search was conducted in good faith, and you believe that no such literature exists, indicate "**No literature exists**" in the space below this text border.*

IV. Amendments

1. Is the protocol being amended per this submission?_____**Yes**_____**No**
If yes, an Amendment Review Document needs to be attached to this submission. **Please note that an Amendment may require revisions to the protocol application and/or to the consent form. If applicable, the appropriately revised IRB-1 protocol and/or consent form(s) for review.**

2. Was the protocol amended during the last IRB approval period?_____**Yes**_____**No**
If yes, please list the approval date(s) for each amendment.

Amendment Approval Date(s):

Note: Add additional rows to the table as needed.

Please Note: Submit a revised IRB-1 only if you are requesting approval of an amendment with this re-approval that requires changes to the IRB-1. If you are not amending the IRB-1 per this submission, do not submit an IRB-1. Submit a clean copy of the Consent Form or Information Sheet if participants are still being enrolled.

V. Participants

For each participant population, please complete the following:

Identify each Participant Population in this column (if more than one, identify each)	# of participants approved for the study (inclusive of any approved amendments).	# of participants enrolled (signed a consent form or gave oral consent after reading an information sheet) since last IRB review (continuing or initial).	Total # of participants enrolled to date (all previous years plus this year). See "***Important***" note below.
Total:			

Note: Add additional rows to the table as needed.

Is enrollment proceeding as expected?_____**Yes**_____**No**

If no, please provide a short explanation.

Important: If more participants were enrolled than was approved explain why? Additionally, if you wish to increase the total anticipated enrollment, please explain why?

Report of Participants Screened (if applicable)

Required if the study involves use of an approved screening procedure (often the case with NIH funded studies and/or more than minimal risk studies reviewed by the full board), please complete the following for participants *screened*:

Identify each Participant Population in this column (e.g. Children, Adults)	Since last IRB review, report total # of participants who…		Total # of participants screened *to date* who…	
	Failed screen and were removed by PI	Passed screen and were enrolled into study	Failed screen and were removed by PI	Passed screen and were enrolled into study

Note: Add additional rows to the table as needed.

If data is available, state the number of participants enrolled to date in each of the categories below. This information is required for NIH funded research.

	Liberian (Black)	Other Africans (Black)	White	Other or Unknown	Total
Female					
Male					
Unknown					
Total					

Please Note: If participants were enrolled during the last IRB approval period, you must submit copies of 5 signed Consent/Assent forms to the IRB for verification purposes with the participants' last names blacked-out. Do not provide the IRB with original consent forms. If fewer than 5 participants have been enrolled during the last approval period, copies of all signed Consent/Assent forms obtained during this period must be submitted. If you have used more than one IRB-approved Consent/Assent form, (e.g., Adult, Parental Permission, Assent, Translations, etc.), please submit at least one example of each type used.

VI: Events to be Reported at Re-Approval

Please Note: Adverse Events and Protocol Deviations, both anticipated and unanticipated, must be reported in writing to the IRB in accordance with the Adverse Event/Protocol Deviation policy. Please see the IRB website for further information. Place your response BELOW, not within, the box containing each item's description.

Were adverse events and/or protocol deviations reported to the IRB during the

last approval period?_____Yes____No

If yes, please list the IRB acknowledgment letter date(s) for each event in the table below. Note: a description of these previously reported events is NOT required.

Adverse Event/Protocol Deviation Acknowledgement Date(s):

Note: Add additional rows to the table as needed.

1. *Describe any previously unreported events that were not serious and were not related to study procedures.*

2. *Describe if the frequency of these event(s) was different from what you anticipated. Indicate "Yes" or "No." If yes, please explain in the space below the text border.*

3. *Did the PI or member of the research team remove a subject from the study during the last approval period? Indicate "Yes" or "No." If Yes, please describe how many participants were removed and the circumstances/reasons for each removal. Include your opinion about whether any of the removals were related to the research procedures.*

4. *Did any participant voluntarily withdraw from the study since the last IRB review? Indicate "Yes" or "No." If yes, indicate how many subjects withdrew, and at what point during the study they withdrew (i.e., after consenting but before study procedures were initiated). Describe if this number is more or less than expected. Also, if known, please state the reason(s) for withdrawal.*

5. *Were there any complaints about the research since the last IRB review? Indicate "Yes" or "No." If Yes, please describe how many, the nature of the complaints, and how they were addressed.*

Vll. IRB Review By Other Institutions

Has another IRB reviewed this study?_____Yes____No

If yes, provide the name of the institution(s) and describe the outcome(s):

Name of Institution(s): **Important -** Please attach the current, unexpired approval/re-approval letters from each institution associated with this study.	Indicate Approval Period:	Outcome of Review (e.g. approved, require modifications, deferred, not approved). **Important:**. If the study was not approved or was deferred, please explain in the space below the table.

Note: Add additional rows to the table as needed.

VIII. Comments From the Principal Investigator

If applicable, please provide additional comments that may be helpful in the IRB's evaluation of the continuation of this study.

Principal Investigator Certification

I understand the Atlantic Center for Research and Evaluation (ACRE) IRBpolicies concerning research involving human participants and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by the Government of Liberia, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring agency;

3. To obtain prior approval from the IRB before amending the research protocol or the approved consent/assent form;
4. To report to the IRB in accordance with IRB policy, any adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5. To submit the Re-Approval/Completion Form as needed;
6. That my participation and the participation of any co-investigators does/do not violate the UL-PIRE IRB policy on Individual Conflicts of Interest in Research;
7. That each individual listed as study personnel in this application has a) completed the required human subjects training, and b) are knowledgeable of the study procedures described in the protocol;
8. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

Original Signature of Principal Investigator	**Date**

Original Signature of Co-I (Only in Absence of PI)	**Date**

Section 25.06 Material Transfer Agreement Template

Date: _____

Materials Transfer Agreement Governing the Transfer of

Samples and Biological Materials

The purpose of this letter is to provide a record of the biological material transfer from the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the ACRE IRB Code for Health Research Ethics and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of this agreement. The RECIPIENT organization's Authorized Official will also sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward a copy of this agreement to the ACREIRB in Liberia after which approval for proposed research will be given by the IRB. The PROVIDER SCIENTIST will send the biological materials to the RECIPIENT SCIENTIST as outlined in the research protocol approved by the IRB. This Implementing Letter is effective afterthe IRB issues approval for the research. The parties executing this Implementing Letter certify that their respective organizations are conversant with and accept the authority of the ACRE IRB, and further agree to be bound by its terms, for the transfer specified above. Please fill in all of the blank lines below:

1. TITLE OF RESEARCH:

   _____

   _____

2. IRB ASSIGNED PROTOCOL NUMBER: _____
3. ORIGINAL MATERIAL (Enter description):

   _____

   _____

   _____

4. PROVIDER (Organization providing the ORIGINAL MATERIAL)
    a. Name of Organization:

    _____

    b. Street Address:

    _____

    _____

    _____

    c. City/State: _____
    d. Phone/Fax: _____
    e. E-mail: _____

    _____

    f. Signature of Head of Provider Institution/Date:
5. PROVIDER SCIENTIST
    a. Name and Title: _____
    b. Street Address:

    _____

    _____

    _____

    c. City/State: _____
    d. Phone/Fax: _____
    e. E-mail: _____

    f. Signature/Date: _____
6. RECIPIENT SCIENTIST
    a. Name and Title: _____
    b. Street Address:

    _____

    _____

    _____

    c. City/State: _____

d. Country: _____

e. Phone/Fax: _____

f. E-mail: _____

g. Signature/Date: _____

7. RECIPIENT ORGANIZATION CERTIFICATION (Organization receiving the ORIGINAL MATERIAL)

I hereby certify that the RECIPIENT organization has accepted and signed the Materials Transfer Agreement (this may be the RECIPIENT SCIENTIST if he/she is authorized by the RECIPIENT organization)

a. Name of Organization: _____

b. Street Address:

_____

_____

_____

c. City/State: _____

d. Country: _____

e. Phone/Fax: _____

f. E-mail: _____

g. Signature of authorized official/Date: _____

h. Name and Title: _____

8. In response to the terms of the research protocol titled _____

_____

_____, the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following:

a. The above BIOLOGICAL MATERIAL is being made available to the RECIPIENT for the sole purpose of research outlined in the protocol named in this letter only. Within the context

of this research proposal only, the MATERIALS, their modifications and progenies are jointly owned by the parties to this agreement.

b. The BIOLOGICAL MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the BIOLOGICAL MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the BIOLOGICAL MATERIAL available, under a separate MATERIALS TRANSFER AGREEMENT, to other scientists who wish to replicate the RECIPIENT SCIENTIST's research.

c. Any BIOLOGICAL MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE BIOLOGICAL MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the BIOLOGICAL MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECPIENT, or made against the RECPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.

d. The RECIPIENT agrees to use the BIOLOGICAL MATERIAL in compliance with all applicable statutes and regulations, including, for example, the ICH GHP Guidelines, 1992 UN Convention on Biological Diversity and those relating to research involving the use of human and animal subjects or recombinant DNA.

e. The BIOLOGICAL MATERIAL is provided at no cost other than as specified in the research protocol.

f. The BIOLOGICAL MATERIALS are to be stored at

_____

_____and used at the laboratories of the RECIPIENT SCIENTIST and collaborators under the RECIPIENT SCIENTIST's direct or delegated supervision as specified in the research protocol approved by the IRB.

g. Without written consent from the **PROVIDER**, the **RECIPIENT** and/or the **RECIPIENT SCIENTIST** may NOT provide **MODIFICATIONS** for **COMMERCIAL PURPOSES**. It is recognized by the **RECIPIENT** that such **COMMERCIAL PURPOSES** may require a commercial license from the **PROVIDER** and the **PROVIDER** has no obligation to grant a commercial license to its ownership interest in the **MATERIAL** incorporated in the **MODIFICATIONS**. Nothing in this paragraph, however, shall prevent the **RECIPIENT** from granting commercial licenses under the **RECIPIENT's** intellectual property rights claiming such **MODIFICATIONS**, or methods of their manufacture or their use.

h. If the **RECIPIENT** desires to use or license the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES**, the **RECIPIENT** agrees, in advance of such use, to negotiate in good faith with the **PROVIDER** to establish the terms of a commercial license. It is understood by the **RECIPIENT** that the **PROVIDER** shall have no obligation to grant such a license to the **RECIPIENT**, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the **MATERIAL** to any third party(ies), subject to any pre-existing rights held by others.

i. The **RECIPIENT AND PROVIDER** as joint owners are free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **MATERIAL**.

j. The **RECIPIENT** agrees to use the **MATERIAL** in compliance with all applicable statutes and regulations, including ICH GHP Guidelines, WHO Code for Health Research Ethics and institutional regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

k. This Agreement will terminate on completion of the **RECIPIENT's** current research with the **MATERIAL**, after which full ownership reverts to the PROVIDER and the **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**.

The RECPIENT and the RECIPIENT SCIENTIST should sign both copies of this letter and return one signed copy to the PROVIDER SCIENTIST. The PROVIDER will then forward the BIOLOGICAL MATERIAL. the PROVIDER SCIENTIST shall provide signed copy of this agreement to the IRB.

(a) Appendix: Section of National Code for Health Research relating to MTA

(n) Materials Transfer Agreement

Transfer of samples and biological materials such as animals, herbs and plants out of Liberia shall require a Materials Transfer Agreement (MTA) detailing the type of materials, anticipated use, location of storage outside Liberia, duration of such storage, limitations on use, transfer and termination of use of such materials subject to any law, regulations and enactment in Liberia.

The purpose of MTA is to protect the interests of local researchers and Liberia's human and natural resources in all its biodiversity as well as how they can be legitimately used. It ensures that the interests of all relevant parties, human and community participants in research and the Liberian nation are protected from exploitation and egregious harm.

(a) The MTA shall be signed by all parties involved in the research including local and international principal investigators, heads of local institutions, research sponsors and other relevant parties.

(b) IRB shall review the MTA to ensure consistency with the stated objectives of the research, the contents of the informed consent documents and the principles enumerated above. The IRB shall grant provisional approval pending the submission of MTA to IRB and receipt of acknowledgement from the IRB.

(c) The applicant for research review shall file a copy of the MTA and provisional approval by the institutional IRB with the IRB for record purposes only.

(d) IRB shall acknowledge receipt of the MTA to the applicant who shall inform the institutional IRB.

(e) Institutional IRB shall grant final approval to research involving international transfer of Liberian samples after all other criteria stated in this code for approval of research has been met and upon receipt of acknowledgement of MTA.

(f) The MTA does not vitiate the right of research participants or communities to request that their samples be withdrawn from research according to the terms of the informed consent process.

REFERENCES

Human Research Protection Program Institutional Review Board Standard Operating Procedures (SOPs), Purdue University. *Updated July 1, 2019*

University of Cape Town Faculty of Health Sciences Human Research Ethics Committee Manual of Standard Operating Procedures. *Last Revised July 2018*

University of Virginia Standard Operating Procedures for the Human Research Protection Program. University of Virginia IRB SOP. Version Date: July 11, 2017.

Hubert Kairuki Memorial University Standard Operating Procedures (SOPs) For Institutional Research Ethics Committee (IREC); Second Edition 2015; The Institute Of Postgraduate Studies And Research, 70 Chwaku Street, Regent Estate, Mikocheni. P.O.Box 65300 Dar Es Salaam. www.hkmu.ac.tz

National Ethics Committee /Comite National D'ethique (RNEC) Standard Operating Procedures; SOP's Version 2, January 2009. Assurance No. FWA 00001973, IRB 00001497 of IORG 0001100, Ministry of Health, P.O.Box 84, Kigali, Rwanda.

ACRE-Africa Center Institutional Review Board (IRB) Standard Operating Procedures, Ground Floor, GD Building, University of Liberia, Monrovia, Liberia. February 2008.