UNIVERSITY FOR DEVELOPMENT STUDIES

STANDARD OPERATING PROCEDURES FOR ETHICS REVIEW OF RESEARCH INVOLVING HUMANS AND OTHER LIVING ORGANISMS

UNIVERSITY FOR DEVELOPMENT STUDIES INSTITUTIONAL REVIEW BOARD

TAMALE

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ABBREVIATIONS AND ACRONYMS

CFR	: Code of Federal Regulations
CoI	: Conflict Of Interest
CIOMS	: Council for International Organizations of Medical Sciences
DHHS	: Department of Health and Human Services
DSA	: Data Sharing Agreement
DSMB	: Data Safety Monitoring Board
DSMC	: Data and Safety Monitoring Committee
EC	: Ethics Committee
EPA	: Environmental Protection Agency
FDA	: Food and Drugs Authority
HoS	: Head of Secretariat
IND:	Investigational New Drug
IRB	: Institutional Review Board
MTA	: Material Transfer Agreement
NIH	: National Institutes of Health
PI	: Principal Investigator
REB	: Research Ethics Board
SAEs	: Serious Adverse Events
SOPs	: Standard Operating Procedures
UDS	: University for Development Studies
WHO	: World Health Organization

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INTRODUCTION

The University for Development Studies Institutional Review Board (UDSIRB) ensures that appropriate procedures and processes exist to safeguard and protect the rights, safety and welfare of research subjects. In fulfilling these responsibilities, the UDS IRB shall review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. Examples of documents that the IRB shall review include: applications/protocols, consent/assent document(s), research equipment form, tests, surveys, questionnaires and similar measures, and recruitment documents. Before any human subject or living organism is involved in research in relation to this University, the IRB will give proper consideration to:

1. The risks to the subjects;
2. The anticipated benefits to the subjects and others;
3. The importance of the knowledge that may reasonably be expected to result:
4. The informed consent process to be employed; and
5. Conflict of interest and integrity of the research process.

The establishment of the IRB is deemed necessary to enable UDS accomplish its mandate as reflected in its vision of becoming 'the home of world class pro-poor scholarship'. The University strives to achieve its ideals by ensuring that there are conscious intellectual and pragmatic inputs into the development processes of the poor and socially excluded segment of society in Ghana.

The establishment of the UDS IRB is principally aimed at fulfilling the requirement of standardizing the conduct of research efforts within the University, its catchment area and Ghana as a whole. As an elite academic and research institution, the UDS IRB is committed to making sure that its research activities meet international ethical standards. The IRB will focus on research protocols with direct links to the UDS. These shall include research directly initiated by UDS researchers and those from outside the institution but affiliated with or in collaboration with the UDS.

The UDSIRB membership, terms of reference and operating procedures shall be guided by existing national and international guidelines and regulations which have been adapted to suit the local context. Membership to UDS IRB shall be drawn from a wide spectrum of individuals and institutions of high repute from within and outside Ghana.

This document provides Standard Operating Procedures (SOPs) to facilitate the work of UDS IRB. The SOPs shall go through regular annual reviews to provide up-to-date standards that guide research to meet both domestic and international requirements.

1.0 VISION

The UDS IRB envisages becoming a world class centre for ethical excellence for the review and evaluation of research protocols involving humans, animals, other organisms, genetically modified materials and the environment.

2.0 MISSION STATEMENT

The UDS IRB seeks to achieve its vision by:

1. Putting in place appropriate measures to guarantee the independence of the Board in the review and evaluation processes of protocols and deciding on the ethical merits of research with humans, animals, other organisms, genetically modified materials and the environment;
2. Ensuring that all available human and material resources are harnessed to facilitate the improvement of research in northern Ghana in particular and Ghana in general through appropriate research activities; and
3. Ensuring and protecting the rights, dignity and safety of all individuals and communities who participate in research activities undertaken by UDS and its stakeholders.

3.0 RESPONSIBILITIES OF THE UDS IRB

The UDS IRB shall:

I. a. Review protocols submitted by researchers from the UDS and other research institutions in Ghana and abroad proposing to conduct scientific research related to humans, animals, other organisms, genetically modified materials and the environment.

   b. Pay special attention to studies that may include vulnerable participants such as children, prisoners and mentally challenged people among others.

II. Act in the full interest of actual or potential research participants and concerned communities, taking into account the interests and needs of researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

III. Ensure that only approved investigators are allowed to conduct proposed studies. This shall be done by considering relevant qualification, training and experience, as

documented by current curriculum vitae and/or by any other relevant documentation.

IV. Provide ethical oversight through monitoring of approved projects.

V. Suspend, withdraw approval or stop research projects that the IRB approved but have proved to be harming participants to an extent that makes the risk/benefit ratio ethically unacceptable.

VI. Ensure that research results have potential benefit to the participating individuals/communities and are disseminated to policy makers to enable translation into policy and/or interventions.

VII. Provide initial review, continuing review and review of amendments of research protocols as detailed in these SOPs.

VIII. Give ethical support and advice to researchers, policy makers and any other stakeholders.

IX. Make efforts to conduct community outreach activities so as to sensitize communities about scientific research and research ethics.

X. Concern itself strictly on the scientific and ethical merits of submitted protocols for approval; executing the tasks free from bias or influence.

XI. Organize regular training and awareness creation on ethics and good research practices for students and staff.

XII. Assist investigators in the submission process by making available the following documents:

3.1 Institutional Materials

The following documents which are either available in the Secretariat or online will be relevant for the application process

a) IRB standard operating procedures
b) Meeting schedule
c) Protocol submission form
d) Sample consent form and consent form checklist
e) Protocol amendment form
f) Adverse events reporting form
g) Protocol deviation/Violation form
h) Final report form
i) Study closure form

3.2 Other relevant materials include:

a) Federal Policy for the Protection of Human Subjects "Common Rule Policy"
b) Code of Federal Regulations: 45 CFR Part 46 DHHS, NIH
c) The Belmont Report
d) Council for International Organizations of Medical Sciences(CIOMS) Guidelines
e) The Declaration of Helsinki (current version)
f) The WHO Guidelines
g) UDS Ethics Policies
h) Other reading materials on human subject protection.

4.0 MEMBERSHIP

4.1 Composition

The Vice Chancellor of UDS shall be the appointing authority of members of the UDS IRB.

I. The UDS IRB membership shall be drawn from within UDS and other institutions.
II. Each institution shall be represented by a primary IRB member and an alternative (substitute) IRB member who will act in the absence of the primary member.
III. Members shall be selected based on their interests, knowledge and expertise as well as their commitment and willingness to volunteer the necessary time and efforts for the Board's work.
IV. The appointing authority shall consider age and equal opportunities for all gender and relevant but diverse professional representation in the appointment of IRB members.
V. Appointed members should be able to read and understand the official language (English) in which the protocols are written.
VI. As mandated by International Ethical Guidelines and Regulations, at least one member of the UDS IRB shall be a clinical scientist, one non-clinical scientist and one community representative.
VII. A lawyer shall be appointed.
VIII. A representative from the Teaching Hospital shall be appointed.
IX. The UDS IRB shall be independent of the Vice Chancellor of the UDS, researchers, sponsors and any other stakeholders in its review and decision-making processes.

4.2 Terms/Conditions of Appointment

I. In accordance with international guidelines, the UDS IRB shall consist of a reasonable number of members, a minimum of 15 members, who collectively have the

qualification and experience to review and evaluate the science, medical, social and ethics of research protocols.

II. The Vice Chancellor of UDS shall appoint the Chairperson of the IRB.
III. Equal opportunities should be given to all gender.
IV. Any member who has any vested interest in a protocol submitted to the Board for review under the terms and references of the Board shall make known to the Chairperson and shall not participate in the deliberations of the protocol.
V. Members shall be willing to publicize their identity, name, profession and affiliation to the UDS IRB.
VI. Members shall be willing to sign and abide by the confidentiality agreement regarding meeting deliberations, applications, protocol submissions, information on research participants and related matters which they have had the privilege to have as a result of being members of the IRB.
VII. UDS IRB members shall be appropriately compensated.

4.3 Tenure of Office:

I. Membership shall be for a period of three (3) years.
II. Membership may be renewed only once. However, at least one-third of the old members shall be retained for an additional one year. The maximum tenure of office of Board members is six (6) years.
III. Since the IRB Administrator is a permanent employee of the C entre, his/her tenure is not limited provided he/she is still employed by the UDS.

4.4 Termination of Membership

I. Membership may be terminated voluntarily by resignation.
II. The Chairperson may resign by sending his/her resignation letter to the appointing authority after duly informing the Board in a meeting.
III. For any voluntary resignation, a prior notice of at least one month should be given
IV. Membership shall be terminated by the appointing authority on the advice of the IRB if a member is going to be away for more than one year.
V. Membership shall be terminated by the appointing authority upon advice by the IRB if a member has been absent from three consecutive meetings without any apologies.
VI. Membership shall be terminated by the appointing authority for misconduct that tarnishes the credibility of the IRB as determined and advised by the IRB.

VII. Membership shall be terminated if a member is convicted by a court of competent jurisdiction for a criminal offence.

VIII. Membership shall be terminated by the appointing authority in consultation with the IRB if a member is suffering from chronic incapacitating illness that significantly reduces his/her ability to process information and make rational independent decisions.

5.0 ADMINISTRATION AND FUNCTIONS

5.1 Secretariat

I. The IRB shall have a dedicated Secretariat located at UDS.

II. The IRB Secretariat shall have office space for the Administrator, the administrative assistants and IRB documents. There shall be a well-furnished meeting room for UDS IRB work.

III. IRB documents shall be properly secured.

5.2 Operations

I. The operations of the IRB Secretariat shall be spearheaded by the Administrator of IRB secretariat in consultation with IRB Chairperson.

II. The operations of the IRB secretariat shall be separate from and independent of the administration of the UDS.

III. Applications to the IRB shall be channeled through the IRB Secretariat.

IV. All decisions and communications from the IRB to applicants shall be conveyed by the Secretariat.

V. The staff of the IRB Secretariat shall comprise the following:

1. IRB Administrator; and
2. Support staff.

VI. The Secretariat shall be made up of full-time employees of the institution where the IRB is based.

VII. The Secretariat shall be managed by an administrator who shall be knowledgeable about Research Ethics and be provided with periodic training.

VIII. The Secretariat may have support staff who are not members of the IRB.

IX. The UDS shall provide the necessary funding for the operations of the Secretariat.

5.3 Responsibilities of the Administrator

The Administrator shall be of a Deputy Registrar rank. He/she shall:

i. Support the Chairperson of UDS IRB in preparing and providing a statement of assurance when required by the regulations guiding the establishment of the IRB.
ii. Conduct IRB meetings in accordance with all the regulations.
iii. Prepare and provide a statement of assurance when required by the regulations guiding the establishment of the IRB.
iv. Facilitate the provision of training and educational programmes to new and continuing IRB members.
v. Perform a pre-review of each submission to the IRB to ensure adherence to administrative submission requirements.
vi. Review and accept revisions made per committee recommendations for onward submission to the Board for consideration.
vii. Determine submissions that are exempt from review, and notify the Chairperson of the IRB and the submitting investigator of such exemptions.
viii. Supervise the staff of the Secretariat.
ix. Issue approval letters and other documents.
x. Design and disseminate templates for IRB submission documents, including research protocols, informed consent materials, agreements and periodic and final reports.
xi. Design and maintain a system for collecting and filing all IRB documents, including minutes of, member qualifications, protocol submission versions, deviations from approved protocols, and periodic and final reports.
xii. Secure all documents of the Secretariat.
xiii. Be responsible for any other duties that may be assigned.

5.4 Responsibilities of the Support Staff

The support staff shall:

I. Help with clerical work as assigned by the IRB Administrator
II. Perform any assigned responsibilities by the Chairperson, the IRB and the Administrator.
III. Not review proposals or offer any advice to applicants regarding the contents of submitted applications.
IV. Keep information that they are exposed to in the IRB Office private and confidential and also sign private and confidentiality forms as well as conflict of interest forms upon joining the IRB Office.

5.5 Responsibilities of the Chairperson

The Chairperson shall:

I. Chair and conduct IRB meetings in accordance with all regulations
II. Assign responsibilities and duties to the other members of the IRB.
III. Supervise the Administrator.
IV. Be the final approving authority for all IRB certification and documents.
V. Submit annual reports on the operations of the IRB to the Vice-Chancellor.
VI. Enforce all rules and regulations of the Board.
VII. Perform any other duties assigned by the Board.
VIII. Perform expedited review of research that meets the expedited review criteria.
IX. Be responsible for determining whether a submitted protocol qualifies for exemption from review, expedited review or full Board review.
X. Depending on the decision of the Chairperson on a particular protocol, primary reviewers could be appointed to review the protocol.

5.6 Responsibilities of IRB Members

Membership becomes effective upon accepting an invitation from the appointing authority. The responsibilities of members shall include:

I. Supporting the Chairperson in the discharge of his/her duties.
II. Undertaking duties assigned to them by the Chairperson.
III. Studying critically documents submitted to them before meetings.
IV. Being willing to have his/her full name, profession and affiliation(s) published in the public domain.
V. Maintaining absolute confidentiality of all IRB documents in their possession.
VI. Attending meetings regularly and participating actively during deliberations.
VII. Declaring any conflict of interest for any protocol, and withdrawing from the review process of that particular protocol.
VIII. Submitting updated CVs to be kept on file at the IRB Secretariat.

New members shall undergo an orientation exercise upon joining the Board in order for them to familiarize themselves with the SOPs and receive training on basic Research Ethics. Such training shall be organized by the IRB Secretariat, UDS and/or any other players involved.

Continuous training of IRB members on Research Ethics and other relevant areas including experimental designs shall be organized regularly.

6.0 PROTOCOL SUBMISSION

This section highlights the procedures for submitting documents to the UDSIRB for ethical clearance. Applicants are required to adhere to the following instructions:

I. The Principal Investigator of a protocol is responsible for following protocol submission procedures as outlined in these SOPs;
II. The IRB Administrator is responsible for receiving and processing new protocol submissions, and for ensuring that all elements required for consideration are present; and
III. The submitting investigator will submit a research protocol to the IRB through the Administrator.

6.1 Submission Procedures

I. The applicant shall submit 15 bound copies of the full research protocol and an electronic version. In addition, applicants shall submit soft copies in pdf format to the irb@uds.edu.gh or upload at http://www.udsirb.edu.gh. Otherwise, these should be sent together with a covering letter to the Secretariat of UDS Institutional Review Board, University for Development Studies, P.O. Box TL 1350,Tamale, Ghana.
II. The deadline for submission of documents to the UDS IRB for full Board reviews shall be within the following dates:
    - First Quarter Meeting - 15th February;
    - Second Quarter Meeting - 15th May;
    - Third Quarter Meeting - 15th August; and
    - Fourth Quarter Meeting - 15th November

    All other applications shall be handled on roll-on basis.
III. The Secretariat of UDSIRB shall acknowledge receipt of the application document, and indicate its completeness or otherwise in writing.
IV. If the Board is in need of supplementary information, the applicant shall supply it using the next quarter's deadline.
V. Applicants are also required to submit a signed checklist indicating all documents submitted to the Board.

VI. The UDS IRB shall provide a fair and transparent review of all applications. In line with this, applicants can apply to the Board for a review of its own decisions. Such applications shall be accompanied with relevant information indicating the shortfalls in the previous actions or decisions of the Board.

VII. Applicants can apply to the Board for permission to amend their protocols before or after the review. Applicants seeking to amend their protocols before the review shall do so in three (3) clear weeks prior to the meeting of the Board. Those seeking to amend their protocols after the review shall submit their application within the stipulated time period for that quarter's meeting.

6.3 Detailed Instructions on Amendments

The PI shall prepare the amendment package and submit to the IRB Administrator. The amendment package shall include:

a. A letter stating the reasons for the amendments;
b. A completed protocol amendment form (available at the UDS IRB Office);
c. A list of the amendments and their location in the protocol/consent form(s);
d. The protocol/consent form(s) with tracked changes indicating the amendments effected;
e. A clean version of the protocol/consent form(s) with the changes effected; and
f. The amended protocol/consent form(s) shall be given a new version number and an effective date.

I. At the Secretariat the Administrator shall:

g. Notify the Chairperson of the submission.
h. Send the request for amendment and all related documents to the Chairperson within five (5) working days of receipt.

II. The Chairperson shall determine whether the protocol requires expedited or full Board review. Protocol amendments which increase risk to study participants and therefore require full Board review may include but not limited to:

a. Additional treatments or the deletion of treatments;
b. Any changes in inclusion/exclusion criteria;
c. Change in method of dosage formulation, such as, change of oral medications to intravenous;
d. Significant change in the number of subjects (a change of 5% is considered significant); and

e. Significant decrease or increase in dosage amount.

III. If an amendment is received just prior to the meeting of the Board, the Chairperson may decide to review the amendment at a full Board meeting, even though the amendment may qualify for expedited review.

IV. The Administrator shall take note of recommendations for changes to the protocol and/or informed consent requested by the Board in the minutes and communicate the decision to the investigator in writing.

V. If the Board does not approve the amendment(s), the notification to the investigator shall state the reason(s) for not approving the amendments.

VI. If the Board requires modifications to any of the documents, the specific changes required shall also be communicated to the investigator instructing him/her to make the necessary changes and resubmit the documents to the Board.

6.4. Administrative Requirements

I. The applicant must be the Principal Investigator (PI) or co-PI of the proposed research project.

II. Protocol Application Form should be completed, signed, and dated by the PI/co-PI or his/her designee.

III. All international collaborative researches shall have a local principal investigator.

IV. Student applications shall be submitted under the responsibility of a Faculty member or in the name of the student, co-signed by a Faculty supervisor.

V. All the documents, including the covering letter must be written in English Language. In instances where the original documents are not written in English Language, the documents shall be accompanied with an English Language translation.

6.5 Protocol Contents

Protocol contents should include summary of the study, background/introduction, rationale, objectives (general and specific), clear-end points, methodology, recruitment strategy, laboratory investigations to be done (where applicable), plans for analysis and publication, personnel, budget & justification and time frame of the project, dissemination plan and community sensitisation.

The following documents should also be submitted:

i. Subject enrolment forms;

ii. Data collection tools such as questionnaires, interview /discussion guides, checklists and case record forms;
iii. Serious Adverse Events forms;
iv. Consent forms (i.e. the study information sheet and consent form in English and translated into the major local languages of the study site(s) as well as their back translation into English).
v. All materials to be used in 'advertising' the research project, campaign materials, brochures, etc; and
vi. Up-to-date CVs of PI and or co-PIs (CVs shall be dated and signed and shall not be older than six months). Bio-sketches of Co-Investigators should be submitted although full CVs may be demanded by the IRB.

6.6 Other Requirements (for an Interventional Study):

1. For clinical trials, an insurance certificate covering damages on participants and errors in the protocol implementation;
2. Material Transfer Agreement (MTA) if applicable;
3. Data Sharing Agreement (DSA) if applicable; and
4. A list of members of the Data Safety Monitoring Board (DSMB) if applicable.

Applications may also be submitted for the following purposes:

1. **Continuing review after the initial review:** to report on the progress of research and to secure continuing approval of protocols requiring UDS IRB review; and
2. **Amendments to approved protocols**: to request for any changes/or additions to approved protocols relating to recruitment methods, informed consent procedures, study design and research personnel.

7.0 MEETINGS

The Administrator shall prepare and submit all necessary documents to UDS IRB members two (2) clear weeks prior to the ensuing meeting.

7.1 IRB Meeting Schedule and Distribution of Agenda

I. The UDSIRB shall meet quarterly.
II. In the event that the Board is unable to convene, the IRB Chairperson shall provide an alternate meeting time and date.
III. The Chairperson shall lead UDSIRB meetings. In the absence of the Chairperson, the Vice-Chairperson shall lead the meeting. In the absence of both the Chairperson and

the Vice Chairperson, the IRB members shall select an Acting Chairperson to chair the current meeting provided there is a quorum.

IV. The selected Acting Chairperson shall sign minutes of the previous meeting confirmed during his/her Chairpersonship.

V. The Acting Chairperson shall not have authority to sign IRB official documents such as approval letters.

VI. The IRB Administrator or his/her appointed representative shall notify all IRB members of an upcoming meeting at least one week in advance. The notification will include a meeting agenda, which shall outline all protocol and related research submissions for consideration in the meeting.

VII. The IRB Administrator shall notify all members of any changes in meeting time, date or agenda as soon as discovered.

VIII. The IRB Administrator shall keep an archive of all copies of meeting agenda and all other documents.

7.2 Meeting Procedure

I. The IRB Chairperson shall call the meeting to order only when there is a quorum. Two-thirds of IRB members must be present to form a quorum, including at least one member from the Humanities and one from the Natural Sciences.

II. If the Board reviews an application that involves participants vulnerable to coercion and/or undue influence such as children, prisoners, cognitively impaired, one or more individuals knowledgeable about or experienced in working with such participants must be present.

III. If a quorum is not formed, the meeting should be rescheduled.

IV. At the end of the meeting, the IRB Administrator shall retrieve and archive all documents.

7.3 Review Procedures

If the meeting is to review a new submitted protocol, the following procedure shall be followed:

I. The protocol should have already been reviewed by a Sub-committee constituted by the Chairperson and the comments of the Sub-committee incorporated into all submitting documents before forwarding them for ethical approval.

II. The Principal Investigator of that protocol may be present to make a brief presentation of the protocol to the Board and to answer questions that will be raised by members of the Board.

III. The Board shall critically review the ethical concerns that the particular protocol raises according to the principles of Autonomy, Beneficence and Justice.

IV. The Board reserves the right to invite any individual who is not a Member of the Board but has the necessary expertise to help in the review of a particular protocol. This person shall have no voting rights.

V. Voting on a protocol shall be determined either by consensus or by ballot.

VI. In the event of a tie, the Chairperson shall have a casting vote.

VII. The Chairperson shall ensure that a quorum is maintained at every point in the review process.

7.4 Participation of Principal Investigator in IRB Meetings

I. The IRB Administrator will notify all Principal Investigators of the meeting scheduled to consider their submissions at least two weeks before the meeting date. The Administrator will also notify all PIs about their protocol's place in the agenda. A co-investigator may attend on the Principal Investigator's behalf if necessary.

II. The Principal Investigator may be invited to the meeting during consideration of his or her protocol to make a short presentation.

7.5 Approval Procedure

I. Each IRB Member shall vote for, against or abstain from a protocol. An absentee Member is allowed to send in his/her comments but cannot vote.

II. In order for a protocol to be approved, it shall receive the approval of a majority of members present at the meeting. The IRB may also decide to postpone decisions on a protocol if more information or consideration is required.

III. An approval letter shall state the frequency of continuing review, the documents that were reviewed and approved with their version numbers and dates and a reminder to the investigator to seek prior IRB approval before implementing any modification to the approved documents.

IV. UDS IRB approvals shall be subject to the approval of continuing review reports. If the IRB decides to disapprove a research protocol, the IRB shall include in its written notification to the investigator a statement of the reasons for its decision, and will give the investigator an opportunity to respond in person or in writing.

7.5 Emergency IRB Meeting

I. Emergency IRB meeting shall be held if there is an urgent issue or issues that do not qualify for expedited review but require a full IRB meeting.
II. A quorum is required for the emergency meeting to be held.
III. The Secretariat shall circulate a notice giving the date, venue, time and agenda of the emergency meeting at least 48 hours before the day of the meeting.
IV. Relevant documents shall be made available to the IRB members in advance, at least 24 hours before the date of the meeting.
V. Minutes of the emergency meeting shall be confirmed in the next scheduled IRB meeting.

7.6 Conflict of Interest (CoI)

The UDS IRB is committed to avoiding any possible financial and non-financial CoI of IRB members, experts to the IRB, and research staff for all IRB-approved research activity. It is the responsibility of the Administrator and the IRB as a whole to ensure that members and experts who review research protocols have no conflicting interest.

Conflict of Interest is defined as a situation in which a person, such as a public official, an employee, or a professional has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are two main categories of this definition – Non-Financial and Financial CoI.

7.6.1 Non-Financial

I. ***Personal Relationship***: The IRB member or expert has a personal relationship (e.g., spouse, domestic partner, immediate family member or close friend, kinship or ethnic affiliation) with the PI or key personnel (e.g. involved in the design, conduct or reporting) of a research protocol under review.
II. ***Relationship to the Research Study:*** The IRB member or expert (or his/her spouse, domestic partner or immediate family member) is involved in the design, conduct or reporting of the research protocol under review.
III. ***Business Relationship or Affiliation***: The IRB member or expert to the IRB (or his/her spouse, domestic partner or immediate family member) serves as a trustee, director, officer, owner or partner of a for-profit entity that could be affected by the outcome of the research protocol under review by the IRB.

7.6.2 Financial

The IRB member or expert (or his/her spouse, domestic partner or immediate family member) has a financial interest that could be affected by the outcome of the research protocol under review.

7.6.3 Determination of CoI.

At the beginning of each IRB meeting, the IRB Chairperson shall query IRB members of possible CoI for any of the full review items listed on the agenda. CoI shall be declare das follows:

I. Disclosures shall be made by IRB Chairperson to the IRB members.
II. Disclosures shall be made by IRB members or experts to the IRB Chairperson.
III. The IRB Chairperson, or IRB members shall determine whether a conflicting interest exists.
IV. At the time that research documents are submitted for IRB review, the IRB Administrator shall screen the documents to determine if any IRB member is listed as key personnel for the study. If it is determined that an IRB member has a CoI, that member will not be assigned as a reviewer;
V. Upon receiving the IRB agenda one week prior to the IRB meeting, IRB members are encouraged to notify the IRB Administrator if they have any CoI with studies on the agenda;
VI. IRB members with a CoI will not be counted toward the quorum;
VII. In the event that a quorum cannot be met because of CoI recusals, the Chairperson shall co-opt additional experts to consider that specific application; and
VIII. The determination of whether or not a conflict exists shall be reflected in the IRB minutes.

7.6.5 Recusal

a. IRB members who have a CoI related to any research protocol to be considered must refrain from participating in any discussion of the protocol or related matters except to the extent necessary to provide relevant, factual information requested by the IRB, and may not deliberate or vote on those protocols or related matters.
b. Unless requested by the IRB to provide information to the IRB, the IRB member or expert with a CoI will be required to leave the room for the final discussion and vote. An IRB member assigned to carry out an expedited review for a protocol or related

matters with respect to which a CoI has been identified, must notify the IRB Chairperson or Administrator so that the protocol may be reassigned.

c. Any member of the IRB either voting or non-voting who contravenes the above will be sanctioned by terminating the protocol review process. In addition, the member will be relieved of his or her membership of the Board. Where approval has already been given the certificate shall be withdrawn.

8.0 INITIAL REVIEW

The ethics review processes of the UDS IRB require applicants to provide thorough information about their research projects and the steps they will take to minimize risks and maximize benefits to humans, animals, plants, other living organisms, genetically modified materials and for the wellbeing of the ecosystem. Applications for UDS IRB clearance may be for different purposes, based on the policies of the UDS IRB, the nature of the research, and new developments during the research.

Applications may be for initial review, which could be for:

1. Full Board review
2. Expedited review
3. Exemption from review

8.1 Full Board Review

For research that poses risk and requires full review by UDS IRB to assure that the risk can be minimized, the following must be adhered to:

I. All new research protocols involving members of the UDS must undergo initial review by the UDS IRB in order for the research project to be granted approval before commencement.

II. All new research protocols by investigators not employed by UDS, but the proposed research is to be conducted in UDS, must undergo initial review by the UDSIRB in order for the research project to be granted approval before commencement.

III. Initial review of research protocols should be done by a full IRB, unless it qualifies for expedited review and there is acceptable justification for the expedited review as per the relevant SOPs of the IRB.

IV. Full protocol as per IRB requirements shall be submitted.

V. The IRB shall assess the perceived social impact and/or value of the proposed research.

VI. The IRB shall assess the scientific merit and validity of the proposed research.

VII. If human participants are to be recruited, the inclusion and exclusion criteria shall be assessed for ethical and scientific appropriateness.

VIII. The IRB shall assess the informed consent process to ensure that the following pertinent aspects are covered:

a. Adequate privacy and voluntariness of participants
b. Satisfactory procedure to ensure confidentiality

The IRB shall determine the appropriateness of the informed consent process for the category of people to be enrolled in the study. These shall include:

a. Provision for community consent, individual consent, proxy consent and assent;
b. Duration of contact with potential participants to seek consent;
c. Non-technicality of the consent form and its completeness;
d. Provision for vulnerable populations;
e. Provision for consenting potential participants without formal education; process to eliminate undue inducement;
f. Provision to continue providing study information to participants throughout the study period; and
g. Process of ensuring confidentiality.

IX. The IRB shall also examine the information sheet and informed consent form for the following:

a. Purpose of the research;
b. Foreseeable risks;
c. Potential benefits;
d. Confidentiality;
e. Voluntariness;
f. Local contact information (PI and IRB contacts should be included);
g. Signature options (to include a witness in the case of an illiterate participant);
h. Compensation; and
i. Brief questions to assess comprehension.

X. Potential risks already stated in the protocol and any other that may have been omitted but are deemed likely to occur should be assessed in the light of potential benefits.

XI. Criteria for withdrawal or discontinuation of participants should be assessed to ensure fairness and safety of participants.

XII. If a placebo is to be used, there must be scientifically and ethically acceptable evidence-based justification that must be clearly explained in the protocol.

XIII. The recruitment process should be suitable for the targeted prospective participants and their communities in terms of cultural, traditional, religious or socio-economic factors.

XIV. Research shall be conducted on or with vulnerable groups such as women, children, prisoners and mentally and physically challenged people only if the research questions cannot be answered when non-vulnerable groups are used.

XV. Relevant mechanism(s) of monitoring and auditing the conduct of the research must be clearly spelt out in the protocol.

XVI. In the case of international clinical trials, Data Safety and Monitoring Board (DSMB) should be set up and should provide names and contacts of members, one of whom should be a national of at least one of the host countries.

XVII. In the case of clinical trials, there shall be documentary evidence of insurance policy to cover trial of participants.

XVIII. If the research project involves more than one institution and samples are to be shipped from one institution to another, a signed Material Transfer Agreement between the sample or data provider and the recipient must be submitted to the IRB.

9.0 EXPEDITED REVIEW

This is applicable to research activities that may not pose risk or pose minimal risk to human participants. The Chairperson in collaboration with the Administrator shall determine which protocols may require expedited review.

The following shall qualify for an expedited review:

I. Research activities that present no or minimal risk to human subjects and other living organisms and the environment;

II. Minor changes in previously approved research protocols;

III. Amendment to the study protocol that does not in any way increase risk to study participants;

IV. Protocols involving interviews not likely to harm the status or interest or offend the sensibility of study participants;

V. Collection of data for research purposes through non-invasive procedures routinely employed in clinical practices and using medical devices which have already been approved for use. Examples of such procedures include non-invasive blood pressure and other routine clinical measurements;

VI. Research involving data, documents or specimens that have already been collected or shall be collected for ongoing medical treatment or diagnosis; and

VII. Continuing review of a protocol previously approved with no modification to the original protocol and the study has taken place and no additional risk has been identified.

9.1 Specific Procedure

I. Expedited review shall be conducted by the Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the Board. If the review involves a revised version, the selected members shall normally be members who reviewed the previous version of the protocol.

II. The expedited review of a revised protocol shall be carried out on the complete study protocol with all required attachments as if it was being submitted for the first time. Results of the review process may be communicated to the PI before being discussed at a Board meeting.

III. Expedited review shall not take longer than two(2) weeks. In an expedited review, the reviewers may exercise all of the authorities of the Board. However, if the outcome of the review merits disapproval, it should be recommended to the Chairperson for further review by the full Board.

IV. A research activity may be disapproved only after review in accordance with the non-expedited procedure is done. If the outcome of the expedited review is that of disapproval, the protocol shall go for full Board review. The Administrator shall inform all members about the outcome of an expedited review as soon as practicable.

V. A summary of the protocols reviewed through an expedited process shall be submitted to members before full Board meeting.

10.0 EXEMPT REVIEW

This is applicable to research activities that may be eligible for exemption from UDS IRB review. That is, research studies which are of minimal risk, does not subject to a

formal consent process or to continuing review by the IRB. Risk means "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*" (45 CFR 46.102(i)) see reference 6 under "References"*.

a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour unless:
    i. Information obtained is recorded in such a manner that human subjects can be identified, directly or *through identifiers linked to the subjects;* and
    ii. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
b. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigators in such a manner that subjects cannot be identified**,** directly or through identifiers linked to the subjects.

IRB protocols approved for exemption are not subject to continuing review; however any proposed modification to the protocol will necessitate re-evaluation of the protocol's exempt status.

10.1 Determination

It is the responsibility of the UDS IRB to make all determinations of exemption. Identification of research projects that qualifies for exemption shall be made by the Chairperson or by one or more qualified IRB members designated by the Chairperson.

11.0 PROTOCOL AMENDMENT

11.1 Submission Procedures

Amended protocols should be resubmitted according to guidelines described in Section 6.0 above.

12.0 CONTINUING REVIEW

I. The IRB Chairperson and IRB members are responsible for determining whether the research is reviewed annually, or more frequently appropriate to the degree of risk.

II. The IRB is also responsible for determining whether an independent Data and Safety Monitoring Board is required.

III. The PI is responsible for keeping the IRB informed of significant findings that affect the risk/benefit ratio and thus the need for more frequent review. The investigator is also responsible for following the continuing review procedures and deadlines as outlined in these SOPs.

12.1 Determination of Frequency of Continuing Review

I. At an initial protocol review of a research activity, the IRB shall determine:

a. How often it will re-evaluate the research project. All research will be reviewed at intervals appropriate to the degree of risk, but not less than once per year;

b. The factors to be considered in setting the frequency of review should include the nature of the study, the degree of risk involved, and the vulnerability of the study subject population; and

c. Whether these studies need verification from sources other than the investigator; that no material changes in the research have occurred.

II. The investigator on a long term project (more than 12 months) shall utilize the continuing review form to complete semi-annual review report. The report shall include all required elements, including the following:

a. Number and demographics of participants enrolled;

b. Changes in principal and/or co-investigator(s);

c. A summary description of subject experiences;

d. Any serious adverse events experienced;

e. Numbers of and reasons for withdrawals from the research;

f. The research results obtained thus far;

g. A current risk-benefit assessment based on preliminary study results; and

h. Any new information since the IRB's last review.

III. If the investigator cannot provide any of the required information, he/she shall provide justification for the delay in the report, and a time-table for provision of the information. The investigator shall also submit a copy of the consent documents and procedures currently in use.

IV. The investigator shall submit one hard copy of the continuing review report, with original signature. The investigator is also encouraged to submit an electronic/pdf copy of the review report via e-mail.

V. Upon receipt of the continuing review report, the IRB Administrator shall conduct a pre IRB review to ensure all the required elements are present. The IRB Administrator shall work with the submitting investigator to ensure all elements are present before distribution of meeting items. The IRB Administrator will place the continuing review report on the next meeting's agenda.

VI. The IRB Chairperson may elect to invite an independent or alternate reviewer to the meeting.

VII. IRB members shall consider and vote upon all continuing review reports in a full-board meeting utilizing the protocol voting procedure. The risk/benefit ratio may change over time. The criteria the IRB uses to approve or disapprove continuation of research are the same as the criteria for approval of an initial research project.

VIII. The IRB shall review the consent process and documents to determine whether they are still accurate and complete, whether new information that may have been obtained during the course of the study needs to be added, and whether the documents being used by the investigator have current IRB approval.

IX. After reassessment, the IRB may require that the research be modified or halted. The IRB may also impose special precautions or relax special requirements it had previously imposed on the research protocol. The IRB shall also determine whether there are any important new findings that might affect the willingness of participants to continue participating in the research. If so, IRB shall require the Investigator to notify the participants of these findings.

12.2 Timing of Continuing Review

I. If the IRB has not reviewed and approved a research study by the study's current expiration date, IRB approval has expired and research activities should stop. No new subjects may be enrolled into the study. However, if the PI is actively pursuing renewal with the IRB and the IRB believes that an over-riding safety concern or ethical issue is not involved, the IRB may permit the study to continue for the brief time required to complete the review process.

II. If the PI cannot provide any of the required information, the PI shall provide justification for the delay in the report, and a timetable for provision of the information. The PI shall also submit a copy of the consent documents and procedures currently in use.

13.0 FOLLOWUP REVIEWS

13.1 Follow up Review Circumstances

I. In general, the UDS IRB shall perform a review of the human research protections programme on an annual basis.

II. The IRB shall conduct audit reviews of ongoing research when complaints or allegations of non-compliance are made.

III. When decisions by regulatory authorities such as EPA, FDA, to suspend a study in whole or in part.

IV. When unexpected events related to study conduct and/or product occur.

13.2 Follow Up Review Procedures

I. Documents to be reviewed: Progress reports, final reports, safety reports, audit reports, monitoring reports, experiences of participants, suspension, termination or completion of study reports.

II. Quorum: Depending on the category of UDS IRB approval (e.g. Exempt, expedited or full board)

a. For Exempt: the approving member or designated member

b. For expedited: the Administrator/Chairperson plus 1 designated UDS IRB member

c. Full Board: at least 1/3 of members of IRB

14.0 DELIBERATION AND DECISION MAKING

In deliberations and making decisions on applications for ethics research review, the UDS IRB shall take the following into consideration:

I. Members shall discuss the various issues before arriving at a consensus decision.

II. A member shall recuse him/herself from the meeting during the decision making process concerning an application where there arises a conflict of interest. The conflict of interest shall be indicated to the Chairperson prior to the review of the application and recorded in the minutes.

III. A decision may only be taken by voting members alone after sufficient discussion.

IV. Decisions shall only be made at meetings where a quorum (as stipulated in the UDS IRB's written SOPs) is formed.

V. The documents required for a full review of the application shall be complete and the relevant protocols shall be considered before a decision is made.

VI. A simple majority decision of voting members is required for approval of applications. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed shall be specified.

VII. A negative decision on an application shall be supported by clearly stated reasons.

VIII. Modified proposals may be reviewed by an expedited review.

IX. Procedures for appeal by the researchers shall be in accordance with the appeal process.

X. Applications with incomplete or incorrect documents shall be returned not later than two weeks after receipt of the application. Inadequacies in the application must be clearly identified in the communication to researchers.

XI. Possible decisions: The UDS IRB can take any of the following decisions on applications:

a. Approved
b. Conditional approval
c. Rejected, with reasons

15.0 COMMUNICATING IRB DECISIONS TO APPLICANTS

The UDS IRB shall communicate its review decisions on different research proposals to PIs and their associates. Although review of protocols may be expedited, exempt, or full, feedback is expected at different stages of the UDS IRB review process.

I. A Full Board review decision shall be communicated within three (3) weeks to applicants after each quarterly meeting.

II. Initial Exempt and Expedited reviews shall be communicated to applicants within one (1) week after a decision has been taken.

III. Appeal decisions shall be communicated to applicants in the same way as in full Board review decisions

15.1 Pre-review Decisions

I. **Initial communication/feedback**: The UDS IRB shall send an email to the PI within 48 hours acknowledging receipt of the protocol, notifying him/her of a designated protocol number for their proposal, and that a second email will convey the UDS IRB determination and categorization of the protocol for review, within 48 hours.

II. **Follow up email**: A second email shall inform the PI of UDS IRB's determination of the category of their protocol and the corresponding time frame for review of such protocols.

15.2 Review Decisions

I. **Approval notification**: A notice of approval of a research protocol shall be formally communicated to the PI. The notification shall, among other things, indicate the date of approval, the fact that approval is given only for the protocol and its associated documents, duration of approval, responsibilities of the researcher (e.g. statement of compliance, progress reports, and requests for another review).

II. **Conditional approval**: The UDS IRB shall state issues that must be addressed before approval is granted. The UDS IRB may also highlight relevant portions needing revisions in an email to the PI. The PI shall submit the revised protocol highlighting effected changes to the Secretariat for further action. Once the Board is satisfied that the revised version has met all UDS IRB requirements, the protocol shall be approved, as in 15.2(I).

III. **Rejected protocols**: The UDS IRB shall communicate the rejection of the protocol to the PI formally. The letter shall state clearly the reasons or other ethical considerations for the rejection of the protocol. The letter shall also encourage researchers to consider redesigning affected research or submit a different protocol for consideration.

All communications related to the protocols shall be signed by the Chairperson or his/her authorized representative.

15.3 Appeal Decisions

A PI may appeal the decision of the Board for reconsideration. An appeal must be reviewed at a full Board meeting, according to the approval procedure described in section 7.5. If the UDS IRB upholds its decision to reject a research project, then the decision cannot be appealed again and this must be clearly communicated to the PI.

Communication of the UDS IRB decision shall include but not limited to the following:

I. The name, title and address of the applicant;
II. The exact title of the protocol reviewed;
III. The name of the site(s) or study area;
IV. The names and identification numbers (versions numbers/dates) of the reviewed documents;
V. The validity period of the approval; and
VI. The Chairperson's or his/her authorized representative's signature on the final approval certificate/letter.

16.0 TRANSLATION OF THE CONSENT DOCUMENT

Definitions

a. ***Translation:*** Conversion of a written document from one language to another.
b. ***Interpretation:*** Facilitating oral communication in more than one language; performed by an interpreter.
c. ***Interpreter:*** A person who translates orally for individuals conversing in different languages.
d. ***Legally authorized representative***: A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects' research, an individual or other body recognized under the laws of Ghana as the guardian/custodian to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

I. It is the policy of the UDS IRB that all documents translated from English to another language should receive IRB review and approval before use, to ensure that the rights and welfare of research participants are adequately protected.
II. It is the Board's responsibility to ensure that non-English speakers are presented with the same opportunity to participate in a research activity as are English speakers. This involves the presentation (written or oral) of the informed consent information in a language understandable to the non-English speaker.
III. The Board shall review and approve any translated documents that were previously IRB approved versions in English.
IV. The translated document is translated back into English. The person providing the back translation must be different from the person providing the original translation.
V. The IRB may invite an expert to review the translated document to determine cultural appropriateness.
VI. A witness, proficient in English and in the research participant's language, must be present throughout the consent process. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.
VII. As a minimum, two of the following signatures are required:

a. The research participant/representative signs the consent form;
b. The witness signs the consent form and the summary;
c. The person obtaining the consent signs the summary; and

d. Additional signature/documentation procedures may be followed as appropriate.

17.0 MONITORING OF ON-GOING RESEARCH

It is the responsibility of the UDS IRB to perform or designate some qualified agents to perform, on its behalf, on-site inspection of the research projects it has approved. The Administrator in consultation with the Chairperson shall initiate an on-site evaluation of a study project.

Specific Procedures

An approved research project to be monitored shall be selected based on the following criteria:

a. The level of risk;
b. Frequency of reports of serious adverse events; and
c. Failure to submit progress report

I. The Board shall notify the PI in writing within one week about plans of the visit.

II. The Board may carry out an unannounced monitoring visit under the following conditions;

a. The PI does not submit a progress report as per the SOPs after two reminders;
b. The PI prolongs research project completion beyond the approved time frame; and
c. The PI is suspected to have changed the objectives and design of the research project without prior approval from the Board.

III. The Administrator shall make the necessary arrangements for the visit. He/she shall also ensure that the monitoring team has all the necessary information to carry out the audit. He/she shall be part of the team that carries out the audit.

IV. The monitoring team shall:

a. Review the informed consent document to make sure that the research project is using the most recent approved version;
b. Observe the informed consent process, if possible;
c. Review the data collection instruments to make sure that the research project is using the most recently approved version;
d. Observe enrolment/recruitment procedures to make sure that they are in accordance with the most recently approved protocol;
e. Observe if there are any protocol violations or deviations;
f. Observe if safety procedures are being implemented;

g. Observe procedures to ensure confidentiality of research project information; and
h. Find out if there are Serious Adverse Events (SAEs) that are not being reported to the Board.

V. The team leader shall:
   a. Conduct a debriefing before departure;
   b. Submit a report within two weeks of the monitoring visit; and
   c. Send a copy of the report to the Chairperson and the PI of the research project.

The Board shall be fully briefed at a scheduled meeting on the visit.

17.1 Data and Safety Monitoring Committee (DSMC)

I. In larger studies or trials, the UDS IRB may also require a DSMC be formed to keep the UDS IRB up-to-date.

II. The primary responsibility of a DSMC is to safeguard human subjects by analyzing accumulating data relevant to the risks and benefits on a regular basis. Especially in long-term trials, the DSMC reviews data periodically to assess effectiveness and toxicity. The DSMC must also decide whether adverse effects are serious enough to warrant termination of the study.

17.2 Serious Adverse Events (SAEs) Reporting

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

II. The primary responsibility of the UDS IRB is to review and address SAE and unexpected events involving risks to subjects or others as well as ethical complaints.

III. Specific Procedures:
   a. The Administrator shall be responsible for pre-screening and processing of the reports. The Chairperson of the Board shall determine the nature of the review.

   The criteria of the review shall be as follows:
   1. If assessment of adverse experience is unknown or unlikely, the report shall be forwarded to the Chairperson for review and determination as to whether the full Board should review the report at the following convened meeting.
   2. If assessment of adverse experience is possibly caused by, or probably caused by the investigational drug, the full Board should add the report to the agenda for review at the following convened meeting.

3. If an adverse experience/investigational new drug safety report has previously been seen by the Board and is being resubmitted by another investigator in the same study (as part of a multi-centre study), this notification shall not require full Board review. The Chairperson or any other qualified Board member will take a decision and report to the Board.

b. In discussing the report, the Board shall determine by vote or consensus on whether to:
    1. Request an amendment to the protocol or consent process;
    2. Request further information; and
    3. Suspend or terminate the study.

c. The Administrator shall formally notify the investigator of the decision.

18.0 WITHDRAWAL OF RESEARCH PROJECT CERTIFICATE AND RE-CERTIFICATION

18.1 Withdrawal of Certificate

I. A project certificate may be withdrawn because the approval conditions are not met.

II. Where a PI misleads or deliberately withholds information from the Board leading to certification, the Board shall withdraw the certificate.

III. The IRB may also withdraw a certificate based on unanticipated problems involving risks, study participants complaints/concerns requiring evaluation, or serious or continued non-compliance of IRB approved procedures.

18.2 Re-certification

It is the responsibility of the PI to promptly notify the UDS IRB, in writing, when suspended or terminated study activities are to be resumed.

I. The PI shall submit a re-certification application to the IRB.

18.3 Review of Final Reports

A review of the final report, which is obligatory, shall be carried out when the last participant has been dealt with and all adverse experiences have been appropriately resolved.

Specific Procedures

a. The PI shall submit a completed final report form (Available at the UDS IRB Office)

b. The PI shall also submit an up to date summary of the activities and, if possible, findings of the study.

c. The Administrator shall brief the Chairperson on the submitted report before making copies and distributing them to all Board members.
d. The Board shall deliberate on the report and decide appropriately.
e. The Administrator shall formally notify the investigator of the decision taken. If no action is required from the PI, the Administrator shall file the final report and consider the study duly closed.

19.0 PROTOCOL DEVIATIONS

A protocol deviation is a minor or administrative departure from the protocol procedures approved by the UDSIRB that was made by the PI without prior approval. Eligibility exceptions are considered changes in research that require UDS IRB review and approval before a subject who does not meet the approved protocol inclusion/exclusion criteria may be enrolled.

I. The following protocol deviations require prompt reporting to the UDS IRB:
   a. **Emergency deviations:** When a deviation occurs in an emergency situation, such as when a departure from the protocol is required to protect the life or physical well-being of a participant, the UDS IRB must be notified as soon as possible, but not later than 5 days after the emergency occurs.
   b. **Non-emergent major deviations without prior approval:** A planned deviation that is non-emergent and represents a major change in the protocol as approved by the UDS IRB must be submitted as a change in research. The IRB must approve the request before the proposed change is implemented. If a major, non-emergent deviation occurs without prior IRB approval the event is considered non-compliant. A PI's failure to report promptly any major, non-emergent deviation for which the PI did not obtain prior approval is itself an incident of non-compliance.
   c. **Protocol deviations that are only minor or administrative:** Minor or administrative protocol deviations are defined as those, which do not *"affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects."* If a protocol deviation occurs which meets this definition, the deviation should be reported to the UDS IRB at the time the continuing review application is submitted. Examples of minor or administrative deviations could include: follow up visits that occurred outside the protocol required time frame because of the

participant's schedule, or blood samples obtained at times close to but not precisely at the time points specified in the protocol.

II. Reporting Requirements: All protocol deviations should be reported immediately, if they represent a significant alteration in the approved protocol and/or if they affect the safety or welfare of the subject, otherwise, the reports should be made during continuing review.

III. Deviations that should be reported to the IRB include the following:

    a. Changes to the research protocol initiated by the investigator prior to obtaining IRB approval (e.g. to eliminate apparent immediate hazards to subjects);
    b. Modification of inclusion or exclusion criteria to mitigate newly identified risks;
    c. Implementation of additional procedures for monitoring subjects;
    d. Suspension of enrolment of new subjects;
    e. Suspension of research procedures in currently enrolled subjects;
    f. Modification of informed consent documents to include a description of newly recognized risks;
    g. Provision of additional information about newly recognized risks to previously enrolled subjects;
    h. Deviations that result in serious breach of confidentiality or privacy;
    i. Specific examples of potentially reportable deviations (i.e., if they place subjects at a greater risk);
    j. Informed consent improperly obtained or not obtained;
    k. Subject enrolled without meeting the eligibility criteria and without prior sponsor approval;
    l. Study drug or dose not administered per protocol and that increases the risk of harm to the subject; and
    m. Unauthorized removal of personal health records offsite, or patient names showing on records that are submitted to the sponsor.

IV. Protocol deviations that lead to SAE should be reported within 72 hours; while protocol deviations that lead to less SAE should be reported within 10 working days.

20.0 PROTOCOL VIOLATIONS

Planned changes to the UDS IRB approved protocol and protocol deviations must be submitted as formal protocol amendments to the UDS IRB for approval prior to initiation or implementation. Outlined below are the two types of violations and how to address them.

20.1 Major Violation

A violation that may impact on subject safety, affect the integrity of study data and the environment and/or affect subject's willingness to participate in the study. These may include the following:

I. Failure to obtain informed consent, i.e., there is no documentation of informed consent. Informed consent obtained after initiation of study procedures.
II. Informed consent for Investigational New Drug (IND) studies obtained by someone other than individuals authorized by UDS IRB to obtain consent, e.g. someone other than a licensed physician investigator.
III. Enrolment of a subject who did not meet all inclusion/exclusion criteria.
IV. Performing study procedure not approved by the UDS IRB.
V. Failure to report SAEs to the UDS IRB and/or sponsor.
VI. Failure to perform a required laboratory test that, in the opinion of the PI, may affect subject safety or data integrity.
VII. Drug/study medication dispensing or dosing error.
VIII. Study visit conducted outside of required timeframe that, in the opinion of the PI, may affect subject safety.
IX. Failure to follow safety-monitoring plan.

20.2 Minor Violation

A violation that does not impact on subject safety, compromise the integrity of study data and the environment and/or affect subject's willingness to participate in the study. Examples include:

I. Implementation of unapproved recruitment procedures
II. Missing original signed and dated consent form (only a photocopy available)
III. Missing pages of executed consent form
IV. Inappropriate documentation of informed consent, including
    a. Missing subject signature
    b. Missing investigator signature

c. Copy not given to the subject signing the form
d. Someone other than the subject indicated on the consent form

V. Use of invalid consent form

VI. Failure to follow the approved study procedure that, in the opinion of the PI, does not affect subject safety or data integrity
   a. Study procedure conducted out of sequence
   b. Omitting an approved portion of the protocol
   c. Failure to perform a required laboratory test
   d. Missing laboratory results
   e. Enrollment of ineligible subject (e.g., subject's age was 6 months above age limit)
   f. Study visit conducted outside of required time frame

VII. Failure of subject to return study drug/substance

VIII. Over-enrolment

IX. Enrollment of subjects after UDS IRB approval of study has expired

X. Failure to submit continuing review application to the UDS IRB before study expiration.

20.3 Reporting Requirements

In reporting a protocol deviation or violation to the UDS IRB, the PI shall complete a protocol deviation/violation form (available at the UDS IRB Office) and provide a summary of the reasons for the deviation. The PI shall also state steps put in place to forestall the future occurrence of such a deviation/violation.

Procedure:

1. All major protocol violations must be reported to the UDS IRB within ten (10) working days of discovery.
2. Minor violations are to be reported at continuing review.
3. It is the responsibility of the PI to determine whether a violation is major or minor and to ensure proper reporting to the UDS IRB.
4. Reports should be made immediately if it represents a significant alteration in the approved protocol and/or if it affects the safety or welfare of the subject. Otherwise, a report should be made during the continuing review.

21.0 DOCUMENTATION AND ARCHIVING

UDS IRB documents and communication shall be dated, filed and archived using appropriate Management Information Systems tools and taking into consideration the Board's policies and written procedures. Such policies and procedures shall not be at variance with the UDS policies and national law.

The Administrator of the UDSIRB shall distribute the SOPs to all UDSIRB members, archive the original paper in both hard and electronic forms, and update the indexed list of SOPs. Any request for extra copies may be made to and fulfilled by the UDSIRB Administrator of the Secretariat.

I. The UDS IRB shall keep a hard or electronic copy or both in a secured environment to ensure confidentiality.
II. Procedures shall outline who is authorized to access the Board's files and documents.
III. Staff of the Secretariat shall be given appropriate training.

21.1 Categories of Documents

There are two categories of documents. These are: Committee/Board-related documents and project-related documents as indicated below.

21.1.1 Committee/Board-Related Documents.

They include:

I. Any document formally establishing the UDS IRB
II. The UDS IRB written Standard Operating Procedures (SOPs)
III. Policies of UDS IRB
IV. Annual reports summarizing UDS IRB activities
V. Updated list of UDS IRB Members
VI. Curricula vitae of all UDS IRB Members
VII. Agenda of UDS IRB meetings
VIII. Minutes of UDS IRB meetings
IX. Regulatory texts used by the UDS IRB
X. Income and expenditure records of UDS IRB.

21.1.2 Project-Related Documents

All project-related documents and materials shall be archived for a minimum period of 5 years and a maximum period of 15 years following the completion of the study. The documents include the following:

I. A copy of all study materials submitted by an applicant;
II. Any correspondence by the UDS IRB with applicants or concerned parties regarding applications, decisions, and follow-up;
III. A copy of initial and follow-up decisions and any advice or requirements sent to an applicant;
IV. All written research/project documentation received during the follow-up including any advice or requirements sent to the applicant;
V. The notification of the completion, premature suspension, or premature termination of a research study;
VI. Progress reports received from researchers as per UDS IRB requirements;
VII. SAEs reports submitted by researchers;
VIII. Final reports from researchers; and
IX. Oversight/monitoring visit reports by IRB members

21.1.3 Disposal of Documents

After the stipulated period of archiving the documents shall be disposed by shredding. Electronic versions should be destroyed in an appropriate manner.

22.0 REVISION OF STANDARD OPERATING PROCEDURES

The SOPs shall be reviewed periodically to meet local and international standards.

22.1 Annual Review

I. The SOPs shall be evaluated for accuracy and timeliness in an annual review. The UDS IRB Administrator shall alert the Board of an annual review requirement.
II. The Board, UDS IRB Administrator or an assigned reviewer will ensure that the SOPs reflect the most current outline of procedures.
III. If the document does not need revision, the author will return the document to the IRB Administrator for recording and filing.

REFERENCES

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada (2014) *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Ottawa: Secretariat on Responsible Conduct of Research
2. Committee on Human Research Publication and Ethics (2010); Kwame Nkrumah University of Science and Technology and Komfo Anokye Teaching Hospital Kumasi, Ghana.
3. Cornell University (https://www.irb.cornell.edu/),
4. Council for International Organizations of Medical Sciences (2002).*International Ethical Guidelines for Biomedical Research Involving Human Subjects*.
5. Council for Scientific and Industrial Research, Ghana (2016). IRB Standard Operating Procedure (SOP). Accra: Council for Scientific and Industrial Research, Ghana
6. Department of Health and Human Services (2009). Federal Policy for the Protection of Human Subjects [The Common Rule (45 Code of Federal Regulations Part 46)].
7. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (1996). *Guideline for Good Clinical Practice*. E6 (R1).
8. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *The Belmont Report*.
9. Navrongo Health Research Centre (NHRC) (2013). Institutional Review Board (IRB)
10. Navrongo Health Research Center (2014). Standards and Operating Guidelines for Ethics Review of Health-Related Research with Human Participants.
11. Princeton University (http://www.princeton.edu/ria/human-research-protection/hrpp-home/),
12. World Health Organization (2011). *Standards and operational guidance for ethics review of health-related research with human participants*, WHO Press, Geneva.

APPENDICES

APPENDIX I

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES

PROTOCOL SUBMISSION REQUIREMENTS

A new protocol must be submitted to the UDS IRB at least two months before the proposed commencement date of the research and must include copies of the following:

1. Protocol Application form(This form is available at the UDS IRB website)

I. A cover letter from the Head of Department where a student is involved indicating that the protocol has gone through a scientific review and has been approved.
II. Full Protocol
III. Summary of protocol
IV. Consent forms (PIs could submit a previously approved consent form. Also see check list of consent form available at the UDS IRB Secretariat. Final English versions should be translated into the dominant local language(s) of the study area and back translated into English and submitted for review)
V. Field guide i.e. questionnaire, enrolment forms, Case Report Forms(Version controlled with effective dates)
VI. Up-to-date curriculumvitaeofboththeprincipalinvestigatorandco-investigators.
VII. *Note: The University for Development Studies Institutional Review Board meets once in every quarter of the year*.

Submit15copiesoftheApplicationto:

The Administrator
UDS IRB Secretariat
University for Development Studies
P.O. Box1350
Tamale
Ghana

APPENDIX II

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES

NEW PROTOCOL SUBMISSION FORM

1. Project Title	
2. Proposed Date of commencement	
3. Principal Investigator	
4. Address of PI	
5. Co-Investigator(s)/Student Investigator(s) a. If student Investigator, indicate status and level of involvement in Research	Status: Undergraduate ☐ Masters level ☐ Doctoral Level ☐ Level of involvement: Thesis ☐Dissertation ☐Assisting faculty ☐Other ☐
6. Collaborating institution(if applicable)	
7. Proposed Project Duration	From:(dd/mm/yy) To:(dd/mm/yy)_
8. Are Other IRs involved in this protocol?	Yes/No If yes, name of IRB _____
9. Funding Status of protocol	Funding pending ☐Funded ☐Not funded ☐
10.Sourceoffunding	
11.ProposedPopulation (Circle all that apply)	a. Males b. Females c. Adolescents(12-18yrsof age) d. Children(under12yrsofage) e. Pregnant women f. Elderly g. Prisoners h. Other_____

12.Proposedsamplesize a. Number of Children: b. Male c. Female	
13.ResearchSite(s)	
14.Isequipmentavailableatthissiteto treat any life threatening adverse events?(Describe)	
15.TypeofStudy(Circle all that apply)	a. Survey b. Case control c. Secondary data analysis d. Clinical trial e. Community based trial f. Longitudinal study g. Other_____
16.ConsentProcess(Circle all that apply)	a. Written b. Oral c. English d. Local dialect e. Other_____
17.Doyouconsiderthisresearch (circle one) Note: Minimal risk is defined as"a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life.	a. Greater than minimal risk b. Minimal risk c. No risk

Name of person completing the form:----------

---------- Role on the study:----------

---------- Signature:----------

Date ----------

For all student projects:

_____ _____ _____ _____

Student Investigator Date *Mentor's Signature Date

**Please note that letter from mentor is also required.*

Please do not fill below (For UDSIRB use only)

Reviewed By:
Date reviewed:
Comments:
Action:

APPENDIX III

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES

APPLICATION FORM

SECTION A: GENERAL STUDY INFORMATION

1. State the title of the proposed research

2. Study Personnel (Only UDS Faculty and appropriate staff may be named as Principal Investigator. All students must list their Faculty advisor as Principal Investigator (PI) below).

Principal Investigator/Faculty Advisor:	
Department:	
Departmental Address:	
Email:	
Phone:	
Student Investigator (if applicable):	
Graduation Year/ level: (e.g., 2017/undergraduate; 5th year/graduate	
Email:	
Phone:	
Study Contact Person:	
Email:	
Phone	

3. List all co-investigators and key study personnel. Provide the name of their department, departmental address, e-mail address, phone number and fax number *(if applicable)*.

Name, Department, Address, E-mail, Phone, Fax

Name, Department, Address, E-mail, Phone, Fax

4. Briefly describe the role of each study personnel listed above (e.g., Research Coordinator, data collection, consent subjects, administer survey, etc.)

Name	Role

5. Indicate type of project

☐Undergraduate Dissertation ☐ Master's Thesis ☐ PhD Thesis ☐ other (describe):

6. Will research be conducted outside of Ghana? ☐Yes ☐No

If yes, complete the Form for Research in a Foreign Country and submit with the application for review.

7. Please list the agencies that are funding or have been asked to fund this research. Attach a copy of the grant application submitted for funding.

8. State approximate dates for starting and ending this research project.(Note: The project must not start until it has been approved by the IRB.)

Start: Finish:

SECTION B: RESEARCH PURPOSE

9. Provide a summary of the purpose of your research project. Include a description of the background and rationale for the study; explain the research design, research methodology, hypotheses and goal(s). Specify the problems to be addressed, what is to be learned, and identify the specific objectives of the proposed research using non-technical language understood by a

person unfamiliar with this area of research.

10. Describe in detail the procedures that will be used to achieve the objectives of the research project and specify what you will do with the results of your study (e.g., publish; share in presentation or conference, **etc.)**

SECTION C: RESEARCH PROCEDURES:

11. Categories of Research: The research involves the following (check all that apply):

☐	Education Research	☐	Internet-based Research
☐	Questionnaires/Surveys	☐	Analysis of Existing Data
☐	Ethnographic/Field Research	☐	International Research
☐	Use of pre-existing/issues	☐	Chart Review–retrospective
☐	EKG/EEG/fMRI/Chest X-ray	☐	Chart Review–prospective
☐	Clinical Observations	☐	Collection of Clinical Specimens
☐	Clinical Tests	☐	Tissue Banking
☐	Drugs/Biologics	☐	Stored Data for Future Use
☐	Audio/Video recording	☐	Other:

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Appendix IV

SECTION D: RESEARCH SETTING:

12. Describe the settings in which research procedures will be carried out (e.g., hospital, clinic, school, home, laboratory, community, farm, natural reserves, prison, etc.)

13. Indicate all UDS campus sites, or off campus sites that are owned or operated by UDS, where the research procedures will be carried out.

14. Is this a multi-site, organization, or institution study? *Note: A multi-site study is any study where the UDS investigator is conducting research at a site(s) that are not owned, operated or under the control of UDS?*

☐Yes ☐No

If yes, please specify the following:

a. Is the UDS Investigator the lead investigator for the multi-site study? ☐Yes ☐No

b. Is UDS the lead site? If no, please specify. ☐Yes ☐No

c. If either of the above is yes, describe the provisions for the management of information obtained from the different sites that might be relevant to the protection of participants (e.g., data coordinating center).

d. List all non-UDS sites where the procedures will be carried out. For each site, specify the contact information and indicate whether the site has UDS IRB approval and/or has granted permission for the research to be conducted at that site.

SECTION E: PARTICIPANT SELECTION AND POPULATION:

Equitable Subject Selection: Selection of subjects must be fair and equitable. That is, the selection process must avoid exploiting potential subjects (taking advantage of their circumstances) and minimize coercion.

Note: In making this assessment, the UDS IRB will take into account the purpose of the research, the setting in which the research will be conducted as well as additional safeguards to protect vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

15. Explain how the subject selection process in this research is fair and equitable, taking into account eligibility criteria, vulnerability and recruitment process:

16. The research involves the following (check all that apply):

☐	Healthy Participants		☐	Prisoners	
☐	Students -- Specify School:		☐	Pregnant Women, Fetuses, or Neonates	
☐	Children or Minors		☐	Cognitively Impaired :	
☐	Children who are Wards of the State		☐	Non-English Speakers	
☐	Employees – Specify Employer:		☐	Institutionalized Individuals (not prisoners)	

17. Please provide a description of the participant population. Describe the characteristics of the participant population such as gender, age range, ethnic background and health status, as applicable to the research.

18. Please provide a rationale for the use of special groups or subjects whose ability to give voluntary informed consent may be in question (e.g., cognitively impaired).

19. Provide the total number of research participants you anticipate are needed for this research (include number of participant records, specimens, etc., if applicable) for IRB approval.

20. In the chart below please indicate the number of subjects per category if known:

	MALE	FEMALE	TOTAL
ADULTS			
CHILDREN			
TOTAL			

21. Will any groups or categories of subjects be excluded from research? ☐Yes ☐No

If yes, please specify and provide the rationale for excluding these subjects:

SECTION F: PARTICIPANT RECRUITMENT PROCEDURES

22. Describe all inclusion / exclusion criteria that will be used to select research participants. Provide a detailed description of how research participants will be selected and by whom.

23. Describe your recruitment plan and attach all recruitment materials including advertisements, emails, flyer, letter of introduction, etc.

24. Check all recruitment materials that apply:

☐	Letter of Introduction	
☐	Recruitment Email	
☐	Flyer	
☐	Advertisements	
☐	Other, please describe:	

25. Will participants be recruited by searching records (e.g., school records, medical records, mailing list, databases, etc)? ☐Yes ☐No

a. If yes, will this include paper files? ☐Yes ☐No

b. If yes, will this include electronic files? ☐Yes ☐No
State who will maintain these electronic files:

c. Will existing data bases be utilized? ☐Yes ☐No

If yes, please specify types and locations of data bases:

d. Other, please describe:

26. Will subjects be offered compensation for participating in the research? ☐Yes ☐No

If yes, describe the nature of the compensation. (Indicate the amount and schedule of payments as well as conditions for subject receiving compensation for participating in the research).

SECTION G: CONSENT PROCEDURES

Unless waived by the UDS IRB, Informed Consent is necessary for all research involving human subjects and must be documented.

Note: For research involving children complete for cognitively impaired subjects.

27. Do you plan to obtain signed documented consent from all study participants? ☐Yes ☐No
If yes, specify the following:

a. Specify where the informed consent process will take place:

b. Specify who will obtain consent and describe their experience in obtaining consent from subjects:

c. How will it be determined that the subjects or the subjects' authorized representatives understand the information presented?

d. If English is not the subjects' native language, will translation be provided? ☐ Yes ☐No

If no, or you plan to use oral consent, please request a waiver of consent or documentation. If you plan to use a consent form or oral script, please complete the template of the UDS IRB and attach a copy for UDS IRB review.

28. Does the proposed research involve deception e.g., through provision of misinformation withholding information etc.? Explain why it is necessary to involve deception(s) in the research.

29. Provide a full account of the debriefing procedures to be followed, if deception will occur. If you plan to debrief, please attach a copy of the written debriefing or the debriefing interview protocol.

SECTION H: RISK TO SUBJECTS:

Risks to research subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society. This section is to assess“benefits” and “risks" to subjects including how those risks may be minimized i.e. the possibility of physical, psychological, sociological, breach of confidentiality, or other harm as a consequence of participation in the proposed research project. Please use as much space as needed to answer each question.

30. Risk Classification: What is the overall risk classification of the research?

NOTE-According to Health and Human Services (HHS) regulations, minimal risk means: "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

☐	Minimal
☐	Greater than minimal

31. What are the possible anticipated risks and discomforts to the participants? Describe all possible risks including psychological, physical, sociological or economic harm (e.g., risk of criminal or civil liability, damage to their financial standing, employability, insurability, reputation, or stigmatization, etc.

    Check all that apply, and describe each:

    ☐ Loss of confidentiality, describe:

    ☐ Loss of social status, describe:

    ☐ Emotional stress or discomfort, describe:

    ☐ Physical injury or discomfort, describe:

    ☐ Loss of employment, describe:

32. Please describe any additional risks to participants or others:

33. Describe how you will minimize these risks and their potential impact to the participants or others?

34 Are there any direct benefits to the research participants? Note: Direct benefit is a valued or desired outcome; an advantage (please do not include monetary inducement or compensation).

☐ Yes ☐ No If yes, please describe.

35. In a few sentences, please address the benefits of the research, both to science and/or society.

36. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits:

SECTION I: CONFIDENTIALITY, DATA AND SAFETY MANAGEMENT:

37. Will you record any demographic data or direct participant identifiers? ☐ Yes ☐ No

If yes, indicate the types of data that will be recorded:

☐	Names	☐	Ethnicity
☐	Addresses	☐	Marital Status
☐	Phone Numbers	☐	Income
☐	Age	☐	Social Security Number
☐	Gender	☐	Job Title / Name of Employer
☐	Other:		

38. Explain why it is necessary to maintain such identifiers and describe the coding system you will use to protect against disclosure.

39. Will you retain a link between study code number and direct identifiers after the data collection is complete? ☐Yes ☐No

If yes, explain why it is necessary and describe the coding system you will use to protect against disclosure (if different from above).

40. Describe what procedures will be used to ensure secure storage of study materials including consent forms, survey responses, etc. during the course of the project. Specify who will have access to these materials:

41. Describe specifically what will be done with all study materials at the conclusion of the study. Include paper records, audio and video recordings, field notes, transcripts, etc. in your response. If materials are to be retained, describe the secure storage of those materials. Please note: Documentation of the signed informed consent of the subjects, written protocol, and other records related to conducted research that are typically held by investigators must be retained for at least three years after completion of the research.

42. In the event that outside organizations are involved (in data gathering, processing, and storage), how will the rights of the subjects be guaranteed by that agency?

43. If your proposed research involves more than minimal risk, describe the Data and Safety Management Plan (DSMP).The DSMP should address:
    a. A description of the plan to monitor research progress and subject reactions, including who will do the monitoring and ensure monitoring will be accomplished
    b. Identification of a Data Safety Monitor or Data Safety Monitoring Committee, where applicable
    c. A plan for dealing with adverse events and unanticipated problems involving risk to subjects or others
    d. A description of the plan to assure compliance with reporting of adverse events and/or unanticipated problems involving risks to participants or others
    e. A description of the plan to assure data accuracy and protocol compliance

SECTION J: TRAINING AND CERTIFICATION:

44. All research investigators who propose to work with human subjects in their studies must have human subjects training.

NOTE: The UDS IRB will not issue final approval unless all proper training is completed or certifications are received.

SECTION K: UNANTICIPATED PROBLEMS OR ADVERSE EVENT

45. Please refer to the section on reporting requirements.

SIGNATURES
Include the signature of the Principal Investigator and the date. Also include the advisor's signature, if applicable.

FACULTY OR STAFF PROJECTS

Principal Investigator (print or type name)	Professional Title
Signature	Date

STUDENT PROJECTS

I am the Faculty advisor for the student submitting this protocol. By my signature, I certify that I have reviewed the protocol and believe that it is scientifically and ethically sound. Furthermore, I believe that the student has the necessary training, experience and knowledge to conduct the research in a manner consistent with the regulations governing human subject research and sound research principles. I agree to:

- Oversee and monitor the conduct of this research by communicating regularly with the student investigator;
- Assist with the solution of any problems or concerns encountered during the research; risks to subjects or others.

I understand that as Faculty advisor I am responsible for the conduct of this research.

Principal Investigator (print or type name)	Professional Title
Signature	Date
Student Investigator (print or type name)	
Signature	Date

APPENDIX IV

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES

SUBMISSION FEES AND PAYMENT INSTRUCTIONS

Proof of payment must be attached to all protocols and amendments that fit in the categories below, on submission ***Note: Researchers must budget for these expenses in their grant application***		
RESEARCH	**REVIEW TYPE**	
Funding Types	**Full committee**	**Amendments**
1. Studies sponsored by UDS/Department/Unit Budgets	(US$ 30.00)	(US$ 10.00)
2. Studies sponsored by Local Ghanaian Organizations	(US$ 200.00)	(US$ 20.00)
3. Studies with international Funding (US$ 15, 000.00 – US$ 500, 000.00)	(US$ 500.00)	(US$ 100.00)
4. Studies with international Funding (< US$15,000.00)	(US$ 500.00)	(US$ 50.00)
5. Studies with substantial International Grants/Contracts (> US$500, 000.00)	(US$ 2000.00)	(US$ 200.00)
6. Non-Ghanaian Investigators with no External Support	(US$ 100.00)	(US$ 10.00)
7. Ghanaian Lecturers/Professionals (Without Funding)	(US$ 10.00)	Free
8. Postgraduate Students with International Funding	(US$ 100.00)	(US$ 10.00)
9. Postgraduate Students with Local Funding	Free	Free
10. Postgraduate Students (Without Funding)	Free	Free
11. Undergraduate Students	Free	Free
12. Non-Ghanaian Students with no External Funding	Free	Free

Note: Applicants will pay the Cedi equivalent at the prevailing rate.

Banking Details

Bank:……. Branch……..

Account Name: UDS Research Ethics Board Account Number…….

US Dollar Number:……. Swift Code:……

APPENDIX V

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES

FORM FOR RESEARCH IN A FOREIGN COUNTRY

Principal Investigator:	
Study Title:	

International Setting: Please complete if your research will be conducted outside of Ghana.

1. Where will the research be conducted?

2. Describe the cultural norms in this setting with respect to research, individual autonomy, consent, age of majority of the target population, etc. in this setting:

3. Will all of the subjects be fluent in English? ☐Yes ☐No

   If no, describe how communication will take place with subjects

Consent

1. Describe how consent will be obtained from subjects: ***(Note*:** Any request for a waiver of the requirements for informed consent must include appropriate justification).

2. Describe how the investigators will ensure that subjects understand the nature of the research:

6. If consent forms are to be used with non-English-speaking subjects, how will translations be obtained? Provide a copy of all translated consent forms for review

Expertise and Consultation

7. What are the investigator's qualifications to conduct research in this setting?

8. Will the investigator be collaborating with local persons (e.g., researchers, universities, community leaders, etc.)? ☐Yes ☐No

   If yes, describe:

9. Does that country where you will be conducting this research require review by a local REB or Ethics Committee? ☐Yes ☐No

   If yes, describe and provide a copy of the notice of approval:

APPENDIX VI

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES

DATA CONFIDENTIALITY AGREEMENT

I, the undersigned, agree to the following:

All data at the individual record level obtained or acquired by the University for Development Studies (UDS) and parties, and given to [*name of principal investigator*] or members of [his/her laboratory/research group] will be coded. Under no circumstances will the identifiers be made available to individuals. Any breach or suspected breach of data confidentiality shall be reported immediately to the Chairperson of the UDS IRB.

In addition, any intentional violation of this agreement shall be the basis for dismissal for cause.

_____
(Signature)

_____
Date

_____
(Print Name)

[Insert information (name, institution, address, etc.) about the data holder here]

APPENDIX VII

INSTITUTIONAL REVIEW BOARD,UNIVERSITY FOR DEVELOPMENT STUDIES

MODIFICATION REQUEST FORM

Please use this form to propose changes to previously approved research. Please direct inquiries to: udsirb@uds.edu.gh

Study Title:		UDS IRB #	
Principal Investigator:		E-mail 1:	
Department:		Phone:	
Study Contact:		E-mail 2:	

MODIFICATION

1. Does this modification involve changes to any of the following? Please check all that apply:

☐	Research Design or Methodology	☐	Study Personnel (Please see training requirement)
☐	Research Procedures	☐	Confidentiality of Data
☐	Recruitment Plan	☐	Number of Subjects
☐	Study Location	☐	Funding Source (Grant Application Required)
☐	Level of Risks to Subjects	☐	Informed Consent/Assent (Revised Documents Required)
☐	Study Population	☐	Study Title
☐Other–Specify:			

2. Please summarize the proposed change for each item checked above.

Select the documents that are being added or updated with this modification. Check all that apply. For each modified document, submit one (1) "Track Changes" version clearly showing the changes from the current version along with one (1) "Clean" version with the changes incorporated.

☐ ☐	Consent/Assent Form(s) Surveys, Questionnaires, Instruments	☐☐ ☐☐	Screening Script(s) Authorization Letter(s)
☐	Revised IRB Application (required)	☐☐	Number of Subjects
☐	Study Location	☐☐	Training Certificate:
☐	Recruitment Material (e.g. ads, study flyers, emails, etc.)		
☐	Other–Specify:		

I, the undersigned PRINCIPAL INVESTIGATOR, acknowledge that no changes/modifications will be implemented prior to the issuance of the UDS IRB Notice of Approval.

NOTE: UDS IRB approval does not replace any departmental or other approvals that may be required.

Principal Investigator/Faculty Advisor's Signature

Date

APPENDIX VIII

INSTITUTIONAL REVIEW BOARD,UNIVERSITY FOR DEVELOPMENT STUDIES

WAIVER OF CONSENT FORM

Principal Investigator:	
Study Title:	

I. Request for waiver of documentation of consent - please complete if requesting a waiver to obtain signed documented consent.

Fill all that apply:

3. The research involves no more than minimal risk, and involves only procedures that do not require written consent outside of research. Please explain:

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. Please explain:

4. Please explain how, in the absence of signed written consent forms, consent will be documented, e.g. tape recordings, videos, chart notes, etc.

II. Request for waiver of informed consent - please complete this section if requesting a full

waiver to obtain consent or waiver of some element(s) of consent.

1. In order to waive some or all elements of informed consent, ALL of the following criteria must be met:

☐ The research involves no more than minimal risk. Please explain:

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects. Please explain:

☐The research cannot be carried out without the waiver or alteration. Please explain:

☐Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain:

APPENDIX IX

INSTITUTIONAL REVIEW BOARD,UNIVERSITY FOR DEVELOPMENT STUDIES
PROTOCOLS FOR UDS IRB CLEARANCE

Protocols for UDS IRB Clearance: Research involving Human Participants[1]

The ethics review processes of UDS IRB require applicants to provide thorough information about their research projects and the steps they will take to minimise risk and maximise benefits to the human participants of the research. Applications for UDS IRB clearance may be for different purposes, based on the policies of UDS IRB, the nature of the research, and new developments during the research, etc.

Applications may be for initial review, which could be for:

1. **Exemption from review**: for research activities that may be eligible for exemption from UDS IRB review;

2. **Expedited review**: for research activities that may not pose risk or pose minimal risk to human participants;

3. **Full Board review**: for research that poses risk and requires full review by UDS IRB to assure whether the risk can be minimised or not
   Applications may also be submitted for the following purposes:

4. **Continuing review** after the initial review: to report on the progress of research and to secure continuing approval of protocols requiring UDS IRB review;

5. **Amendments to approved protocols**: to request for any changes/additions to approved protocols relating to recruitment methods, informed consent procedures, study design, research personnel, etc.
   For each of these applications, a full complement of protocols must be submitted to IRB for action to be expedited on the application. The protocols to be submitted for specific applications may vary in range and depth of information.

Initial applications for new research projects must include the following:

1. **UDS IRB application form** duly signed and dated by the Principal Investigator. For applications for expedited/full Board reviews, the form is available and downloadable from the IRB website at www.irb@uds.edu.gh; and for exempt applications, the form is also available and downloadable here www.irb@uds.edu.gh.

[1]This part of UDS IRB manual is based on the review of best practices of other universities and institutions, particularly Princeton University (http://www.princeton.edu/ria/human-research-protection/hrpp-home/), Cornell University (https://www.irb.cornell.edu/), and The Navrongo Health Research Centre IRB.

2. **UDS IRB template** for consent/release/waiver forms (Written Consent for adults, Oral Consent for adults; Written Parental Permission/Consent Form; Performance Agreement and Release Form; Performance Agreement and Release for Minors), all available at www.irb@uds.edu.gh. (***These forms shall be designed by UDS IRB for use by applicants)***

3. UDS IRB form for Research in a Foreign Country: for research projects outside Ghana.

4. **Protocols of the research**: the survey questionnaire, interview guides, recruitment methods, focus group guides, letters of support, etc., and any materials and language you plan to use with participants.

5. **Verification/Certificate of training** on Research with human participants
6. **Authorization Agreement** to be signed whenever it is needed for collaborative research projects involving one or more institutions.

7. **Confidentiality Agreement** for secondary data: to have the research activities be recognized as not engaged in human participant research.

8. **Certificates of Confidentiality**: allow researchers to refuse to disclose names or other identifying characteristics of research subjects in response to legal demands in order to protect the privacy of human subjects enrolled in a research.

Protocols for **continuing review** include**:**

- UDS IRB **Continuing Application Form** duly signed and dated by the Principal Investigator;

- UDS IRB **Modification Request Form** duly signed and dated by the Principal Investigator;

- **Continuing review application m**ay include all or some of the protocols for initial applications, depending on changes in the research process and the changes in the approved UDS IRB protocols requested.

APPENDIX X

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES
CONTINUING REVIEW SUBMISSION REQUIREMENTS

As stated in the Standard Operating Procedures of the University for Development Studies IRB, a continuing review shall be conducted on all research protocols submitted to the Board. In the initial approval letter of the Board, it shall be stated when investigators are expected to submit progress reports to the Board. The progress report submission shall include copies of the following documents:

1. Completed Continuing Review Form (this form is available at the UDS IRB office) A summary of the protocol
2. Copiesofanychanges/amendmentsmadetotheprotocol/consentformssincethe last approval
3. Astatusreportontheprogressoftheresearchthatincludesanynewinformation ontheresearchthatcouldaltertheIRB'spreviousdeterminationswithrespectto riskstosubjectsorregardinganyunanticipatedproblemsinvolvingrisksonthe study

Progress reports not received by the submission date risk a lapse in IRB approval. This means that all research must stop after the project expiration date.

Note: The University for Development Studies Institutional Review Board sits once in every quarter of the year.

Submit 5copiesoftheApplicationto:

The Administrator
UDS IRB Secretariat
University for Development Studies
P.O. Box1350
Tamale
Ghana

A. Principal Investigator

Principal Investigator:	
Address:	
E-mail address:	
Fax number:	
Phone number:	

B. Protocol Information

1. Title of protocol:	
2. Protocol number:	
3. Funding agency and grant number:	
4. Please indicate grant status: active/pending	
5. Location of research activity:	

C. Protocol Status

1. Pending: If yes, please indicate the reason why the study has not yet begun:	Yes/No
2. Active: If yes, please indicate the month and year the study began: Please indicate remaining duration of the study:	Yes/No (mm/yy)
3. Closed: If yes, please indicate date the study closed: *Please note that if the study is closed, a Request for File Closure must be submitted to the UDSIRB.*	Yes/No

D. Participant Information:

Please state the reason(s) for dropout	
5. Number of participants still to be enrolled	
6. Number of participants scheduled for follow-up	

E. Data Sources

Check all categories that apply to your protocol:

	Human subject intervention with use of informed consent form
	Genetic analysis
	Interviews, questionnaires, tests
	Medical records or other human data
	Other, *please specify***:**

F. Adverse Events or Unexpected Problems

1. Have there been any ***adverse events*** or unexpected Problems in the past approval period?	Yes/No
If yes, please explain in detail and indicate when the UDS IRB was notified of the event or problem. If the UDS IRB was not notified, please explain why this was not done.	
2. Does the study have a Data Safety Monitoring Committee (DSMC)?	Yes/NO N/A
If yes, please indicate the date of the last DSMC review: *Please note that investigators are required to submit DSMC reports to the IRB at the time they are made* *Available to the investigator*.	

G. Protocol Amendments or Revisions

1. Have there been any amendments or revisions to the protocol?	Yes/No
If yes, please indicate the date of the approval from the UDS IRB for the amendment or revision.	
2. Do you wish to submit an amendment at this time?	Yes/No
If yes, please describe the amendment request and rationale for the changes:	
3. Are there new personnel working on this study?	Yes/No
If yes, please list the new personnel	

H. Current Consent Form

1. Please attach a copy of your current consent form for renewal.
2. Is this the original consent form or a revised form? Original Revised

If revised, please provide date of UDSIRB approval for the revision:

I. Protocol Progress Report

1.Pleasesubmita***detailed***progressreport.Theprogressreportmustbesubstantiveandcomplete, and include the goal (s)of the study, findings to-date, and plans for the next year/review period:

J. Publications, Presentations and Recent Findings

a)Have therebeenanypresentationsorpublicationsresultingfromthisstudyduringthepast approval period? Yes/no

Ifyes,pleasesubmitacopyoftheabstract,orthepublication,withthisapplication.

b)Havetherebeenanyrecentfindingseitherfromthisstudy,orarelatedstudy,thatwouldhavean effect on this study's risk/benefit analysis? Yes/No

If yes, please describe and cite references:

Additional Comments:

_____ _____

Principal Investigator Date

Please do not fill below (For UDS IRB use only)

Reviewed By:
Date reviewed:
Comments:
Action:

APPENDIX XI
INSTITUTIONAL REVIEW BOARD,UNIVERSITY FOR DEVELOPMENT STUDIES
PROTOCOL AMENDMENT SUBMISSION REQUIREMENTS

Requestsforprotocolamendmentormodificationstoconsentformsshouldincludethefollowing:

1. A summary of the initial protocol
2. Completed protocol amendment form (forms are available at the IRB office)
3. Summary of the request (investigators must justify why the change is necessary)
4. Copiesoftherevisedocumentsshouldclearlyindicatetheamendmentseffected
5. Clean copies of the revised documents should also be attached
6. Allrevisedconsentformsshouldbesubmittedwiththeirtranslationsintothedominant local languages of the study area and back translated into English
7. Revised documents should not be tampered with.

Note: The University for Development Studies Institutional Review Board sits once in every quarter of the year.

Submit15copiesoftheApplicationto:

The Administrator
UDS IRB Secretariat
University for Development Studies
P.O. Box1350
Tamale
Ghana

PROTOCOLAMENDMENTFORM

1. Project Title	
2. IRB Approval#	
3. Principal Investigator	
4. Address of PI	
5. Type of Amendment (circle all that apply)	a. Protocol amendments b. Modifications to consent form c. Other(specify)
Request(s)(summary of request)	

_____
Name of Person completing this form

_____
Contact Address

_____
Email

_____
Phone

_____
Signature

_____
Date

Please do not fill below this line (For IRB use only)

Reviewed By:
Date reviewed:
Comments:
Action:

APPENDIX XII

INSTITUTIONAL REVIEW BOARD, UNIVERSITY FOR DEVELOPMENT STUDIES

ADULT CONSENT FORM

Please delete instructions in brackets and fill in the necessary information before submitting the consent form.

TITLE OF RESEARCH: *[Insert study title]*

PRINCIPAL INVESTIGATOR: *[Insert Principal Investigator's name]*

PRINCIPAL INVESTIGATOR'S DEPARTMENT: *[Insert Principal Investigator's Department]*

You are being invited to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

Purpose of the research:

[Provide a brief, usually one-paragraph, explanation of what the research is about and state why the subject is being asked to participate.]

Study Procedures:

[Describe all study procedures, including an identification of those that are experimental]

Your total expected time commitment for this study is: *[Insert total time commitment]*

Benefits and Risks:

[Describe any possible benefit to the participants or others that may reasonably be expected from the research.]

[Describe any reasonably foreseeable risks or discomforts to the participants.]

Alternatives

[Describe any alternative procedures that might be advantageous to the subject.]

Confidentiality:

[Describe the extent to which confidentiality of research records, including tape recordings or videotapes if applicable, will be maintained; state whether subjects' information will remain anonymous (if there is no link to their responses and it is not possible at any point to identify the participant) or just confidential; and who will have access to the subjects' data. Sample language is below.]

All records from this study will be kept confidential. Your responses will be kept private, and we will not include any information that will make it possible to identify you in any report we might publish. Research records will be stored securely in a locked cabinet and/or on password-protected computers. The research team will be the only party that will have access to your data.

Compensation:

[Specify whether participants will be compensated and if so, state the form of compensation.]

Who to contact with questions:

1. PRINCIPAL INVESTIGATOR:
   [Insert contact information for Principal Investigator here]

2. If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board at:

   Administrator, Institutional Review Board, UDS

   Phone: ……..

   Email: udsirb@uds.edu.gh

3. I understand the information that was presented and that:

   A. My participation is voluntary, and I may withdraw my consent and discontinue participation in the project at any time. My refusal to participate will not result in any penalty.

   B. I do not waive any legal rights or release UDS or its agents, or you from liability for negligence.

4. I hereby give my consent to be the subject of your research.

If you will consent subjects, but not obtain their signature, delete the below signature lines.

Subject's Signature Date

Person Obtaining Consent's Signature Date

Include if applicable:

Audio/Video Recordings:

[Example:] With your permission, we would also like to tape-record the interview. Please sign below if you agree to be photographed, and/or audio videotaped.

I hereby give my consent for audio/video recording:

Signature…….. Date:…….

APPENDIX XIII

INSTITUTIONAL REVIEW BOARD,UNIVERSITY FOR DEVELOPMENT STUDIES

COMPLAINTOF ALLEGED VIOLATION OF THE UDS IRBCODE OF

A copy of this complaint form and any attachments may be provided to the individual against whom the complaint is filed. The complaint must be signed, in writing, and e-mailed to irb@uds.edu.ghordelivered via postal mail to the address provided on this form for the attention of UDS**IRB Secretariat.**

The UDS IRB does not accept anonymous complaints or complaints filed verbally or via e-mail or facsimile. While the UDS IRB may make reasonable accommodations to protect the identity of the complainant if appropriate and requested, the UDS IRB cannot guarantee anonymity in any case. The IRB's Code of Ethics and other ethics related information is available at UDS IRB website.

DATE: _____

COMPLAINANT (Individual filing the complaint)

Name: _____

Address: _____

Telephone: _____

E-mail: _____

RESPONDENT (Individual against whom this complaint is directed)

Name: _____

Address: _____

Telephone: _____

E-mail: _____

COMPLAINTDOCUMENTATION: Summarize in a written attachment the facts on which this complaint is based and enclose copies of all materials and other evidence that corroborate and support the allegations.

REPORTSTOOTHER ENTITIES: If you have filed a complaint about this same matter to another agency add an attachment showing to whom it was submitted, the approximate date(s), and whether and how the matter was resolved.

COMPLAINANT'S SIGNATURE: I affirm that the statements / information within this complaint are/is correct and truthful to the best of my knowledge.

_____

Signature of Complainant Date

APPENDIX XIV

INSTITUTIONAL REVIEW BOARD,UNIVERSITY FOR DEVELOPMENT STUDIES

UNANTICIPATED EVENT REPORTING FORM

Protocol Information

Report: ☐ Initial ☐ Follow-Up

Event Location: ☐ UDS Site ☐ External Site

Study: ☐ On-site ☐ Multi-Site

Principal Investigator: _____

Department: _____

Phone: _____

Email: _____

Protocol No.: _____

Sponsor/Funding Agency: _____

Protocol Title: _____

Nature of Problem/Event

Check all that apply:

☐ **Serious:** Problem/event is (1) fatal, (2) life-threatening, (3) requires or prolongs hospitalization, (4) produces a disability/incapacity, (5) results in congenital anomaly/birth defect, or (6) requires medical intervention to prevent one of the outcomes listed above.

☐ **Unanticipated:** A problem, event or outcome not already described as a potential risk in the consent form, not listed in the IRB protocol and/or Investigator's Brochure, and not part of an underlying disease or condition.

☐ **Anticipated:** Though described as a risk, the event or outcome has occurred with unexpected severity or frequency.

Problem/Event Summary

Please address each of the following in your summary report of the problem/event.

1. Subject identifier (for purposes of confidentiality, do not identify the subject by name.)

2. Description of the nature of the problem/event

3. Date, time, and location of the problem:

4. Action taken to address the problem:

5. The subject's prognosis or probable outcome:

6. Assessment of causality (i.e., problem/event is *definitely*, *probably*, OR *possibly* associated with this protocol):

7. What follow up measures have been taken or are planned:

Additional questions:

☐ Yes ☐ No should the research protocol and/or informed consent/assent documents be revised as a result of this event?
If yes, enclose revised documents.
If no, explain rationale.

☐ Yes ☐ No Do you plan to notify currently enrolled individuals of this event and/or re-consent subjects?
If yes, describe the method.
If no, explain rationale.

☐ Yes ☐ No Have you complied with all applicable reporting requirements of the sponsors?

Certification by Principal Investigator

My signature certifies the following:

1. All necessary information has been assessed and the attached report has sufficient detail to facilitate UDS IRB review.
2. The risks of the research are minimized to the greatest extent possible.
3. The risk-benefit relationship of the research continues to be acceptable.
4. Check which of the following applies to the consent forms:

☐ The consent form/research protocol does not require revision. Copies of the current documents are attached; or

☐ The consent form/research protocol requires revision. Copies of the current documents are attached; or

☐ The informed consent requirement was waived for this protocol. No copies of consent documents are attached.

Investigator's Signature _____ Date _____

UDS IRB Review

☐ Expedited review sufficient

☐ Full review necessary

Recommended Action(s):

☐ Continue study as submitted and approved by the UDS IRB. No changes necessary.

☐ The informed consent and/or research protocol should be amended to address this problem/event. However, subjects already enrolled do not need to be advised.

☐ The informed consent and/or research protocol should be amended to address this problem/event and subjects already enrolled should be advised appropriately. No new subjects may be enrolled until the IRB has approved the revisions.

☐ Suspend the study pending further review.

☐ Report to Institutional Official.

☐ Other: _____

_____

_____

Reviewer's Comments:

UDS IRB Chairperson's or Designee's Signature _____ Date _____