

UNIVERSITY OF HEALTH AND ALLIED SCIENCES



RESEARCH ETHICS COMMITTEE

(UHAS-REC)

STANDARD OPERATING PROCEDURES

**RESEARCH OPERATIONS OFFICE
INSTITUTE OF HEALTH RESEARCH**

APRIL, 2017.

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1.0 INTRODUCTION

The University of Health and Allied Sciences' Research Ethics Committee (UHAS-REC) is established to review and approve all research planned to be conducted in UHAS facilities and/or involves staff and students of the University. This mandate enjoins the UHAS-REC to provide independent, competent and timely ethical review of research protocols submitted to the Committee with the objective of assuring the safety, dignity, welfare and protection of research participants, and the scientific integrity of work research associated with UHAS. The Committee's operations shall be guided by the Standard Operating Procedures contained in this document.

This Standard Operating Procedures (SOP) of the UHAS-REC outlines the functions, composition and administrative operations of the REC. The SOP describes the mechanism and processes of review of research protocols, types of reviews, amendment procedures as well as procedures for monitoring research, documenting and archiving essential documents. This SOP shall guide the activities of Investigators and REC Members in order to ensure ethical research.

1.1 *Objective of the SOP*

The objective of the Standard Operating Procedures (SOPs) is to contribute to the effective functioning of the UHAS-REC for providing fair, quality and consistent ethical review of research protocols submitted to the REC. These SOPs are intended to complement existing laws, regulations and practices and to serve as a basis upon which research can be reviewed and approved within the UHAS.

1.2 *Roles of the REC*

The pursuit of scholarly work and research will often involve the use of human participants for data collection and analysis. The purpose of the REC in reviewing health related research is to contribute to safeguarding the dignity, rights, safety and wellbeing of all actual or potential research participants, and ensuring the scientific integrity of work associated with the UHAS.

The primary goal of the REC is to protect the rights and welfare of human participants in research studies. The REC will review human participants' research proposals to ensure that:

- The rights and welfare of human participants used in research studies are protected.
- Risks have been considered and minimized.
- The potential for benefit has been identified and maximized.
- All human participants only volunteer to participate in research after being provided with legally effective informed consent.
- Research is conducted in an ethical manner and in compliance with established standards.
- Individuals seeking to conduct such research may not solicit participant participation or begin data collection until they have obtained ethical clearance from REC.
- The REC is authorized to review, approve, require modifications, or disapprove research activities conducted by researchers using human participants.
- The REC will evaluate the science and ethics of the proposed study

Thus the REC in its operations should follow these four key principles of autonomy, beneficence, nonmalficence and justice.

- i. *Autonomy* - respecting the rights, dignity and the ability of research participants to make his or her own decisions and adequately protecting the interest of those who are incapable of making their own decisions.
- ii. *Beneficence* - requires that participants are not harmed by the study and that the benefits outweigh the risks. Research should make a positive contribution towards the welfare of people
- iii. *Nonmaleficence* - research should not cause harm to the research participant(s) in particular or to people in general
- iv. *Justice* - demands that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, sex, economic status, culture and ethnic considerations.

The REC shall:

- i. in its composition, procedures and decision-making be independent of political, professional and/or market influences.
- ii. be responsible for carrying out the review of the protocols for the proposed research studies before the commencement of the studies.
- iii. be responsible for acting in the full interest of potential research participants, the UHAS and concerned communities taking into account the interests and needs of the research participants and having due regard for the requirements of relevant regulatory agencies where applicable.
- iv. ensure that there is regular monitoring and review of the progress of research studies that have been given approval.

1.3 Functions of the REC

The functions are:

- i. To review and approve, recommend modification, or disapprove research protocols submitted to the UHAS-REC Secretariat.
- ii. To ensure that all ethical issues are considered within the protocols submitted for review.
- iii. To monitor the progress of approved studies and to continue the review of research activities at intervals appropriate to the degree of risk but not less than once a year.
- iv. To make available to prospective researchers UHAS-REC administrative information and requirements.
- v. To maintain adequate documentation of UHAS-REC activities, i.e.,
 - Records of all research protocols submitted and reviewed
 - Progress reports submitted by principal investigators (PIs)
 - Records of reported Adverse Events (AEs) and Serious Adverse Events (SAEs)
 - Minutes of REC meetings
 - Records of all monitoring activities
 - Records of all correspondence with PIs
 - Records of all UHAS-REC membership
 - UHAS-REC Standard Operating Procedures (SOPs)
 - Any other records related to the Committee's activities

1.4 Composition of the REC

The REC shall be multidisciplinary and multi-sectorial in composition, including persons with relevant but diverse scientific expertise, balanced age and gender distribution, who have the

qualifications and experience to review and evaluate scientific and health ethics of research protocol. The aim is to constitute a Committee competent enough to review and evaluate all the ethical aspects of research protocols. Independence and competence are the two hallmarks of this ethical and protocol review committee.

The number of persons in the REC should be between ten and fifteen which shall include health professionals of good legal standing, individuals with behavioural and social sciences, members with expertise in legal matters and ethics, and laypersons whose primary background is not in health research.

To ensure that the REC is diverse enough to ensure that multiple perspectives are brought into the discussion, membership will as much as possible be made up of representation from all Schools in the University. The Committee will be supported by an Administrator.

1.5 Terms/Conditions of Appointment

- i. The members shall be appointed by the Vice Chancellor.
- ii. The Chairperson shall be appointed by the Vice Chancellor.
- iii. Members shall be paid honorarium for meetings and monitoring as well as other allowances where necessary. The amount shall be determined by the Vice Chancellor. All allowances paid and reimbursement paid to members shall be documented and subject to public disclosure.
- iv. The Director, IHR, shall be a non-voting member.
- v. Members shall be required to submit their curriculum vitae to the Administrator after nomination for the records.
- vi. Members shall sign a confidentiality undertaking regarding meeting deliberations, application, information on research participants and related matters.
- vii. All members shall at a minimum complete a conflict of interest declaration form at the beginning of each calendar year. Members shall update same at any time in the course of the year.

1.6 Termination of Membership

- i. A member may resign voluntarily from the Committee but should write a resignation letter to the appointing authority through the REC Chairperson.
- ii. For any voluntary resignation, a prior notice of at least one month shall, by courtesy be given.
- iii. The Chairperson may resign by sending his or her resignation letter to the appointing authority after duly informing the committee in a meeting.
- iv. Membership shall be terminated by the appointing authority on the advice of the REC if a member is going to be away for more than one year.
- v. A member who is absent from the meetings three consecutive times without notice shall have his/her appointment terminated.
- vi. Protracted ill health of a member, which does not permit him/her to participate in the deliberations of the REC.
- vii. Membership shall automatically be terminated if a member dies.
- viii. Membership shall be terminated if a member is convicted by a court of law for a criminal offence.

1.7 Independent Consultants

By decision of a properly-constituted REC meeting, named external consultants may be called upon to provide independent expertise to the REC on proposed research protocols, populations or topics. The consultants shall complete the conflict of interest declaration form and the confidentiality statement prior to undertaking the requested work.

1.8 Education for REC members

All REC members shall have training focusing on the following areas:

- i. The roles and responsibilities of the REC
- ii. Full range of ethical considerations relevant to human participants
- iii. The application of such ethical considerations to different types of research
- iv. Basic aspect of research, methodology and design
- v. The impact of different scientific designs and objectives on the ethics of a research study
- vi. The various approaches for recognizing and resolving the tensions that can arise among different ethical considerations and modes of ethical reasoning.

The UHAS shall strive to provide opportunities for members of the UHAS-REC (including Administrative Staff) training that will assure greater efficiency in the work of the UHAS-REC.

1.9 Term of office

- The Chairperson, appointed by the Vice Chancellor shall serve a one-time renewable term of three years.
- A member shall be elected as Vice Chairperson by a majority vote.
- The Vice Chairperson shall serve a one-time renewable term of 2 years.
- For permanently employed officers (Administrator) and permanent members (Director, IHR), their tenure is not limited provided they are still employed.
- Membership shall be 2 years renewable to a maximum period of four (4) years for all other Committee members

2.0 RESPONSIBILITIES

2.1 Responsibilities of the Chairperson

The Chairperson shall

- Conduct REC meetings in accordance with all regulations
- Facilitate the provision of training and educational programs to new REC members, continuing REC members, and the greater science community at UHAS. The training shall include programs about the basic principles of human participant protection, current literature, regulations and guidelines affecting the REC.
- Review and accept revisions that are made per committee recommendation pending protocol approval.
- Determine submissions that are exempt from review, and notify the REC and the submitting investigator of such exemptions.
- Facilitate expedited review of research that meets the expedited review criteria

- Assign responsibilities and duties to a Vice Chairperson or to other members of the REC.
- Supervise the REC Administrator to ensure efficient administration of the REC.
- Be available and attend to any outside investigations by the REC.
- Prepare and provide a statement of assurance when required by the regulations guiding the establishment of the REC.
- Sign REC official documents such as communication to Principal Investigators.

2.2 Responsibilities of the REC Vice- Chairperson

The Vice-Chairperson shall:

- i. Assist the Chairperson in the discharge of his/her duties.
- ii. Perform the same functions of the Chairperson in his/her absence
- iii. Perform assigned responsibilities by the Chair or the REC.

2.3 Responsibilities of REC members

REC membership becomes effective upon accepting an invitation from the appointing authority. Acceptance must be indicated by a dated acceptance letter with the member's signature.

The functions of the REC members include:

- i. Critically review all research protocols submitted to them to safeguard the rights and well-being of study participants
- ii. Attend meetings regularly and participate actively during deliberations.
- iii. Undertake duties assigned to them by the Chairperson.
- iv. To keep REC documents given to them secure, private and confidential and hand them over to the Administrator after final determination.
- v. Sign confidentiality forms as well as conflict of interest forms upon joining the REC.
- vi. Provide updated CVs that will be filed by the REC secretariat.
- vii. Participate in continuing education.
- viii. Members shall declare any conflict of interest for any protocol and withdraw from the review process of that particular protocol.

3.0 ADMINISTRATION OF REC OPERATIONS

For the administration of REC operations, the following procedures shall be followed:

- i. The REC shall have a dedicated office located at the Research Operations Office of the Institute of Health Research, UHAS. This office shall be manned by an Administrator and Support Staff.
- ii. The Office of the REC secretariat shall be restricted to only the Administrator and his/her support staff.

3.1 Operations

- i. The UHAS-REC shall have an Administration that will be headed by an Administrator appointed by the Vice Chancellor, UHAS.
- ii. The operations of the Administration shall be independent of the technical authority of the Vice Chancellor or other Staff of the University of Health and Allied Sciences.

- iii. All technical work of the Administration of the UHAS-REC shall be under the direction of the REC, acting through its Chairperson.
- iv. Administrative authority of the REC Administration shall be a function co-shared by the Chairperson of the REC and the Director, Institute of Health Research, UHAS.
- v. All applications for the review of research proposals shall be submitted to the UHAS-REC through the Administrator of the UHAS-REC.
- vi. All decisions and communications from the REC to applicants shall be conveyed through the Administrator of the UHAS-REC.
- vii. The officers of the REC secretariat shall comprise the following:
 - REC Administrator
 - Other named Support staff
- viii. The Secretariat shall be made up of full-time employees of UHAS.
- ix. The Secretariat shall be headed by an Administrator who shall be knowledgeable about Health Research Ethics.
- x. The IHR, UHAS shall provide the necessary resources and funds for the operations of the secretariat.
- xi. REC documents shall be secured in locked cabinets or shelves accessed by authorized REC secretariat only.

3.2 Responsibilities of the REC Administrator

The REC Administrator shall:

- i. Be responsible for the oversight of REC documents, records and archives.
- ii. Coordinate the review of REC SOPs and forms.
- iii. Maintain a system for collating and filing all REC documents.
- iv. Prepare and submit annual REC plans and budget in consultation with the Chairperson to the Director, Institute of Health Research, UHAS.
- v. Prepare and submit annual reports and other reports on the activities of the Committee.
- vi. Bring to the attention of the REC-Chairperson all correspondence and other important documents received.
- vii. Receive protocols and perform a pre-review of each submission of the REC to ensure adherence to administrative submission requirements.
- viii. Distribute the protocols with all submitted items to REC members in consultation with Chairperson
- ix. Prepare meeting agenda in consultation with the chairperson
- x. Distribute the minutes of the previous meetings to REC members.
- xi. Ensure that all required materials, logistics are available for REC meetings.
- xii. Attend REC meetings and take minutes during the meetings and the decisions taken on each protocol.
- xiii. The REC Administrator shall write the decisions taken by the REC to PIs with the approval of the Chairperson.
- xiv. Correspond with all submitting Principal Investigators (PIs) at all times throughout the submission and review process, while remaining independent of the PIs protocol operations.
- xv. Assist the Chair to conduct REC meetings.
- xvi. Accompany REC member(s) on the monitoring of on-going approved research.
- xvii. Keep information that he/she is exposed to in the REC office private and confidential and shall sign privacy and confidentiality forms as well as conflict of interest forms upon joining the REC office.

- xviii. Keep records of all protocols and approvals and other relevant documents confidential.
- xix. Undertake all administrative procedures in providing training and educational programs to REC members and the greater science community.
- xx. Support the Chair in preparing and providing a statement of assurance when required by the regulations guiding the establishment of the REC.
- xxi. Design and disseminate formats for REC application documents, including research protocols, informed consent materials, agreements, and periodic and final reports.
- xxii. Design and maintain a system for collecting and filing all REC documents, including meeting minutes, member qualifications, protocol submission versions, deviations from approval protocol, and periodic and final reports.
- xxiii. Advise submitting investigators on the preparation and submission of protocols for review according to Standard Operating Procedures (SOPs)
- xxiv. Assist the Chairperson in the conduct of REC meetings.
- xxv. Continually study and update staff about REC operational regulations.
- xxvi. Be available and attend any outside investigations or audits of the Committee.

3.3 Responsibilities of the REC Support Staff

The support staff shall:

- i. Help with clerical work as assigned by the REC Administrator.
- ii. Perform any assigned responsibilities by the REC Administrator.
- iii. Keep information that he or she is exposed to in the REC office private and confidential and shall sign privacy and confidentiality forms as well as conflict of interest forms.
- iv. Not review protocols or offer any advice to applicants regarding the contents of submitted applications.

4.0 REC GENERAL MEETINGS

- i. The Committee shall meet monthly or as may be determined by the Chairperson in consultation with members.
- ii. The REC shall have an agenda for each meeting. The agenda will include listing and identifiers for all research project applications awaiting action by the REC.
- iii. The quorum required for a meeting is one third (1/3) the number of the membership plus one.
- iv. A member who is unable to attend may submit written feedback on protocols he/she has reviewed.
- v. No quorum shall consist entirely of members of only one profession.
- vi. A quorum shall include at least one member who is independent of the University of Health and Allied Sciences.
- vii. Meetings should be planned in accordance with the needs of the workload.
- viii. REC members should be given enough time in advance for the meeting to review the relevant documents. The REC Administrator shall notify all REC members of an upcoming meeting at least two weeks in advance by e-mail and mail. The notification will include a meeting agenda, which shall outline all protocol and related research submissions for consideration in the meeting, and shall include all related materials, including copies of protocols, informed consent materials, continuing and final reviews, safety reports, minutes, amendments and any other necessary documents.

- ix. Minutes of meetings should be recorded; there should be an approval procedure for the minutes.
- x. The applicant, sponsor, and or investigator may be invited to present the protocol or elaborate on specific issue(s).
- xi. Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality undertaking.
- xii. The REC Administrator shall notify all REC members of any changes in meeting time, place, date or agenda as soon as possible.
- xiii. With the exception of applications eligible for expedited review the REC will determine the outcome of its review of research project applications at meetings, where a quorum has been established. All new protocols must be submitted for full board review/approval.

4.1 Procedures for Meetings

- i. The REC Chairperson shall preside over all meetings.
- ii. The Vice-chairperson shall preside over meetings in the absence of the chairperson
- iii. Any member of the REC shall be asked to preside over meetings in the absence of the Chairperson and the Vice-chairperson.
- iv. The REC Chairperson or Vice should follow the agenda for the progress of the meeting. The Chairperson may also choose to deviate from the agenda based on personal judgment.
- v. The meeting shall as much as practicable follow a written agenda.
- vi. A sample of the order of a REC meeting shall be as follows:
 - Chairperson's welcome note
 - Apologies
 - Adoption of agenda, with or without changes
 - Confirmation of minutes of the previous meeting
 - Matters arising from the previous meeting
 - Declaration of conflict of interest
 - New business
 - Any other business
 - Adjournment of the meeting by the Chairperson
- vii. If the meeting is to review a newly submitted protocol, the following procedures shall be followed:
 - The protocol should have already been reviewed by members of the REC.
 - The Committee shall determine the relevance of the proposed study.
 - The Committee shall critically review the ethical concerns that the particular protocol raises according to the principles of Autonomy, Beneficence, Nonmalficence and Justice.
 - The science of the proposed study shall also be reviewed.
 - The Committee reserves the right to invite any individual who is not a member of the Committee but has the necessary expertise to help in the review of a particular protocol. This person shall have no voting rights.
 - Decision on a protocol shall be determined either by consensus or voting. In the event of a tie, the Chairperson shall use a veto to break the tie. The protocol may be approved, disapproved, or deferred until revisions are implemented, additional information is provided, or further expert review is obtained.

- If minor revisions to the submitted documents are required or a missing document of minor importance is to be obtained, the REC may delegate the Chairperson or any competent member to subsequently approve a project which requires revision.
- REC may nominate a competent member to assist the researchers to improve on certain aspects of their proposal.
- The Principal Investigator (PI) of that protocol may be invited through a decision of the REC to make a presentation of the protocol to the Committee and to answer questions that will be raised by members of the Committee.

4.2 Mechanism for Ethical Review

- i. The REC Secretariat shall receive and compile details of all submitted protocols.
- ii. The REC Administrator shall in consultation with the REC Chairperson assign protocols to individual members for review.
- iii. The REC Administrator shall send out copies of all protocols to various members of the Committee as assigned by the Chairperson.
- iv. Members of the Committee should receive the protocols not later than two weeks before the review meeting date.
- v. Members should review assigned protocols within two weeks and submit written feedback to REC Secretariat.

4.3 Submission of Application for Ethical Review and Approval

- All applications for ethical review of research should be submitted to the REC Secretariat.
- All submissions should be done at least three weeks prior to the scheduled REC meeting.

4.4 Application for Ethical Review of Research Protocols

An application for ethical review of a proposed health related research shall be submitted by a Principal Investigator (PI) qualified to undertake the particular study. The PI is directly responsible for the ethical and scientific conduct of the research.

Student applications shall be submitted under the responsibility of a supervisor involved in the oversight of the student's work or in the student's name, co-signed by the supervisor.

The applicant should submit all documents required for ethical review of the proposed research. These may include but not limited to:

- i. Principal Investigator's Application form submission.
- ii. Confirmation letter from participating/collaborative institution involved in the study
- iii. A statement that the researcher(s) agree to comply with ethical principles set out in relevant guidelines.
- iv. Material Transfer Agreement (MTA) for shipment of specimen/biological materials outside of Ghana (where applicable).
- v. Data Sharing Agreement (where applicable).
- vi. Administrative Information on sponsors of the study.
- vii. Completed UHAS-REC administrative information form.
- viii. Completed UHAS-REC checklist.
- ix. Full Protocol with abstract with the following attachments:
 - Signed agreement between sponsor and PI (where applicable)

- Signatory page of key persons of the collaborative institutions involved in the study i.e. Sponsor Signatory Approval Page duly signed, with date (where applicable)
 - Written Informed Consent form (with dates and version number) and translations into the local language (where necessary)
 - Written Parental Consent form & Assent form (where applicable)
 - All data collection forms to be used in the research including but not limited to case report forms, diary cards, questionnaires, interview schedules, etc, clearly indicated and dated
 - Referral forms for treatment (where applicable)
 - All forms, documents, advertisements to be used in the recruitment of potential participants
 - Budget for the study
 - Time line for the study
 - Any other information deemed necessary to facilitate the review process.
 - Current CV(s) of PI & Co-Investigator(s) where same has not been submitted to the REC in the preceding 12 months
- x. Additional requirements for Clinical Trials, Biomedical/Epidemiological Studies:
- Profile on previous study i.e. Phase I & Phase II studies (where applicable)
 - Investigator Agreement (PI's responsibility), Page duly signed, with name and date.
 - Current Certificate of Training in Good Clinical Practice (GCP) for PI(s)
 - Investigational Product Brochure for the study
 - Data Safety Monitoring Board (DSMB) membership and Charter of Work/Current Curriculum Vitae of members.
 - Insurance cover for study participants
 - Data Sharing Agreement (where applicable)
 - Food and Drugs Authority approval letter for use of the Investigational Product/ Devices and clinical trial approval (This should be submitted after REC approval where applicable).
 - Current CV(s) of PI & Co-Investigator(s)
- xi. The applicant shall submit bound copies of the full research protocol (14 copies) and an electronic version.
- xii. PIs must submit complete applications by deadlines that will be set and advertised by the Secretariat of the REC at the beginning of each Calendar Year.
- xiii. It is a requirement of this REC that at least one member of the team of clinical trial investigators be a Ghanaian at a professional rank of no less than the grade of a Senior Lecturer.
- xiv. Additional Requirements by Undergraduates, Masters, Postgraduate, and Fellowship Students.**
- Covering letter and CV of supervisor(s)
 - Covering letter from school
 - Students not taking their academic programme in Ghana are required to identify a local supervisor and submit his/her covering letter and CV

4.5 Standard Operating Procedures for Receiving New Research Protocols

This procedure applies to any of the following research protocols:

- i. Clinical Trial
- ii. Biomedical Studies
- iii. Epidemiological Studies
- iv. Social Science Studies
- v. Fellowship Research
- vi. PhD Research

The procedures for receiving new protocols are as follows:

1. All prospective Principal Investigators shall submit fourteen (14) hard copies of their research protocols with a covering letter to the REC Administrator.
2. The guidelines for the content of the protocols are provided on the UHAS website or the secretariat.

The REC Administrator shall:

- a) Receive the protocol(s) and check to see if the REC requirements for submission has been met
- b) Direct PI to Accounts office for the payment of administrative fees where applicable.
- c) Stamp the protocols indicating the date of receipt.
- d) Record in a register details of the protocols received in the following format:
 - i. Name of the Principal Investigator
 - ii. Title of the Protocol
 - iii. Date received
 - iv. Duration of the Research
 - vi. Nature of the study
 - vii. Type of Protocol received
 - viii. Name and Signature of Person who received the protocol

4.6 Standard Operating Procedures (SOP) for Receiving and Reviewing Undergraduates and Masters Students Research Protocols

The procedures for receiving new Undergraduates and Masters Students protocols are as follows:

Undergraduate and Master's Students protocols shall be considered for expedited review if they meet the criteria.

1. All prospective student Investigators shall submit Fourteen (14) hard copies and an electronic copy of their research protocols with a covering letter from their supervisor to the REC Administrator.

The REC Administrator shall:

- a) Receive the protocols and shall check to see if the REC requirements for submission has been met
- b) Direct PI to Accounts office for the payment of administrative fees where applicable.
- c) Stamp the protocols indicating the date of receipt and who received it
- d) Issue signed receipt administrative form to the PI
- e) Record in a register details of the protocols received in the following format:

- i. Name of the Principal Investigator
 - ii. Title of the Protocol
 - iii. Date received
 - iv. Duration of the Research
 - v. Nature of the study
 - vi. Type of Protocol received
 - viii. Name and Signature of Person who received the protocol
2. Consult with the REC Chairperson the assignment of protocols to specific REC members for primary review.
 3. REC members shall review the protocols and provide feedback to the REC Administrator within two weeks of their receipt of the protocol.

4.6.1 Communicating Review Comments to Prospective Principal Investigators

The REC Administrator shall communicate any ethical issues raised in a formal letter to the students within one week of receipt of the comments.

4.6.2 REC Approval for Implementation

Ethical approval shall be given immediately when no issues are raised by reviewers.

Where there are issues to be addressed, ethical approval shall be granted within one week of the receipt of response(s) from the student investigator when all the ethical issues have been satisfactorily addressed.

4.7 *Standard Operating Procedures for Distributing New Protocols*

4.7.1 This procedure applies to any of the following research protocols

- i. Clinical Trial
- ii. Biomedical Studies
- iii. Epidemiological Studies
- iv. Social Science Studies
- v. Doctoral / post-doctoral research or equivalent

The procedures for distributing new protocols are as follows:

1. The REC Administrator shall compile the protocols received.
2. Consult with the REC Chairperson for the assignment of protocols to specific REC members for primary review.
3. Members shall be assigned to review specific protocols in accordance with their specialty areas and at the discretion of the REC Chairperson.
4. Apart from assigning protocols to specific Members, all other members shall receive copies of all protocols for secondary review
5. Clinical trial protocols shall be reviewed by all members.

4.7.2 Distribution of Protocols to Members

The Administrator shall do the following:

Prepare and compile the protocols received and forward list to the REC Chairperson to assign them to the appropriate reviewers in the following manner.

- a) Date when the protocols were received
- a) Title of Protocol

- b) Name of the Principal Investigator
- f) Names of Assigned Reviewers
- g) Date of distributing Protocols to Assigned Reviewers

The protocols shall be distributed in batches at short intervals (as they are received) to enable REC members have adequate time for the review

The deadline for final distribution of protocols to reviewers shall be not less than **TWO (2) WEEKS** prior to REC scheduled meeting date

4.8 Ethical Review of Research Protocols

All properly submitted protocols should be reviewed in a timely manner and according to an established review procedure.

4.9 Review Process

The following should be considered in the ethical review process:

4.9.1 Scientific Design and Conduct of the Study

- i. The appropriateness of the study design in relation to the objective of the study. The statistical methods (including sample size calculation) and the potential for reaching sound conclusions with the smallest number of research participants.
- ii. The justification of anticipated risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities
- iii. The justification for the use of control arms.
- iv. Criteria for suspending or terminating the research as a whole.
- v. The adequacy of provision for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board (DSMB).
- vi. The adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
- vii. The reporting, publication and dissemination of the research findings.

4.9.2 Recruitment of Research Participants

The characteristics of the population from which the research participants will be drawn should include sex, age, literacy, culture, economic status, ethnicity, etc.

The means by which initial contact and recruitment is to be conducted:

- The full information to be conveyed to potential research participants or their representative should include but not limited to the following:
 - Inclusion criteria for research participants
 - Exclusion criteria for research participants
 - Care and protection of research participants
 - Any plans for withdrawal from the study must be clearly stated and justified
 - The medical care to be provided to research participants during and after the course of the research
 - The adequacy of medical supervision and psycho-social support for the research participants
 - Steps to be taken if research participants voluntarily withdraw during the course of the research

- A description of any plans to make the study product available to the research participants following the research
- A description of any financial costs to research participants
- The compensation for research participants (including money, services, and /or any other items that will be given)
- The provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research
- Insurance arrangements.

4.9.3 Protection of Research Participant's Privacy and Confidentiality

- i. The PI should provide details of how information obtained from participants shall be kept confidential.
- ii. The measures taken to ensure privacy, confidentiality and security of personal information regarding research participants.

4.9.4 Informed Consent Process

- i. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.
- ii. The adequacy, completeness, and understandability of written and oral information to be given to the research participants, and where appropriate, their legally acceptable representative(s).
- iii. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
- iv. Assurance that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety, and well-being).
- v. The provision made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.
- vi. The language should be simple and should not contain scientific jargons.

4.9.5 Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject:

- i. A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation;
- ii. A description of the procedures to be followed and identification of any procedures which are experimental;
- iii. A description of any anticipated risks, harm or discomforts to the subject;
- iv. A description of any benefits to the subject or to others which may be expected from the research;
- v. A disclosure of appropriate alternative procedures or courses or treatment, if any, that might be advantageous to the subject;
- vi. A statement describing how confidentiality of participants' information will be maintained;
- vii. For research involving more than minimal risk, an explanation on what compensation and medical treatment are available should injury occur;
- viii. An explanation of whom to contact in the event of research-related injury to the subject and;

- ix. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled to. The subject may discontinue participation at any time.

4.9.6 Additional elements of Informed Consent

When appropriate one or more of the following elements of information shall also be provided to each subject:

- i. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant) which are currently unforeseeable;
- ii. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;
- iii. Any additional costs to participant that may result from participation in the research;
- iv. The consequences of a participant's decision to withdraw from the research, and the procedure for orderly termination of participation by the participant;
- v. A statement that significant new findings identified during the course of research will be provided to the participant;
- vi. The number of participants involved in the study.

4.9.7 Community Considerations

- i. The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn;
- ii. The steps taken to consult with the concerned communities during the course of designing the research;
- iii. The influence of the community on the consent of individuals;
- iv. Proposed community consultation during the course of the research;
- v. The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research and the ability to respond to public health needs;
- vi. A description of the availability and affordability of any successful study product to the concerned communities following the research;
- vii. The manner in which the results of the research will be made available to the research participants and the concerned communities.

4.9.8 Deliberations and Decision-making

In deliberations and decision making on applications for ethical review, the REC should take the following into consideration:

- i. A member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes;
- ii. A decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of the non-members (e.g., the investigator, representatives of the sponsor, independent consultants)
- iii. Decisions should only be made during meetings where there is a quorum
- iv. The documents required for a full review of the application should be complete and the relevant elements mentioned above should be considered before a decision is made.

Decisions should be made by consensus and if this is not possible, by voting. Each REC member shall vote for, against a protocol or abstain.

- i. An absentee member is allowed to send in his/her comments but cannot vote.
- ii. Clear options for decisions; include approval, conditional approval, a request to revise and resubmit, or disapproval. A disapproval of an application should be supported by clearly stated reasons.

4.10 *Participation of Principal Investigator in REC meetings and Voting Procedures*

- i. The REC 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 behalf of the Principal Investigator.
- ii. The Principal Investigator may be invited into the meeting room during consideration of his or her protocol.
- iii. The Principal Investigator may be invited to make a 10-15-minute presentation on the protocol under consideration. After the presentation, the PI shall remain in the meeting to answer any questions, concerns and suggestions from members.
- iv. After answering questions or issues raised, the Principal Investigator and any other attendees with a potential conflict of interest in the protocol shall leave the meeting during the deliberation period.
- v. The REC members shall deliberate and take the necessary decision on the protocol.

5.0 PROCESS OF REC APPROVAL OF RESEARCH PROTOCOLS

- i. In order for a protocol to be approved, it shall receive the approval of a majority of those members present at the meeting. The REC may also decide to postpone decisions on a protocol if more information or consideration is required.
- ii. 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 REC approval before implementing any modification(s) to the approved documents.
- iii. REC continuing approval of researches shall be subject to the approval of review reports.
- iv. If the REC disapproves a research protocol, it shall notify the PI the reasons for its decision and will give the PI an opportunity to respond in person or in writing.

5.1 *Communicating a Decision*

A decision shall be communicated in writing to the applicant, preferably within one week of the meeting at which the decision was made. The communication of the decision shall include, but not limited to, the following:

- The exact title of the research protocol reviewed;
- The clear identification of the protocol of proposed research or amendment, date and version number (if applicable), on which the decision is based;
- The means and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participant information sheet/material and informed consent form;
- The name and title of the applicant;
- The name of the site(s);

- The date and place of the decision;
- A clear statement of the decision reached;
- Any recommendations by the REC;
- Any requirements by the REC including suggestions for revision and the procedure for having the application reviewed in the case of a conditional decision;

5.1.1 In case of an approval,

- i. Any significant ethical issues that were discussed during the meeting, and the resolution of those issues
- ii. The fact that approval is only given for the protocol and its associated documents as accepted by the REC
- iii. The duration for which the approval is valid, and the procedures to be followed to renew the approval at the end of the period if applicable
- iv. A statement of the responsibilities of the PI to include:
 - Informing the REC when study begins
 - Submission of progress reports at predefined intervals
 - The need to seek further prior- approval from the REC in cases of protocol and or its related documents amendments and deviations

5.1.2 In case of a negative decision, clearly state reason(s) related specifically to ethical considerations and scientific validity.

5.1.3 The name and signature (dated) of the chairperson (or other authorized person) of the REC.

6.0 AD HOC/EXTRAORDINARY REC MEETING

- i. An Ad hoc/Extraordinary REC meeting shall be held if there is an urgent issue or issues that do not qualify for expedited review but require a full REC meeting
- ii. The secretariat shall circulate a notice giving the date, venue, time and agenda of the ad hoc/extraordinary meeting at least 48 hours before the day of the meeting
- iii. The general framework of the agenda shall be as follows:
 - Opening of the ad hoc meeting by the chairperson
 - Apologies
 - Adoption of the agenda
 - The issues for which the ad hoc meeting was convened
- iv. Relevant documents shall be made available to the REC members in advance, at least 24 hours before the date of the meeting.
- v. A quorum should be present for the ad hoc meeting to be held
- vi. The Chairperson shall close the ad hoc meeting
- vii. The minutes of the ad hoc meeting shall be tabled in the next scheduled REC meeting for confirmation and signing.

7.0. CONFLICT OF INTEREST (COI)

7.1 Definition

Conflict of Interest is 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

7.2 Non-Financial

- i. Personal Relationship: The REC member or expert has a personal relationship (e.g., spouse, domestic partner, immediate family member or close friend) with the principal investigator 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 REC 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 REC member or expert to the REC (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 REC

7.3 Financial

The REC 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.

The UHAS-REC is committed to avoiding or managing any possible financial and non-financial Conflict of Interest (COI) of REC Members, Experts to the REC to ensure that the rights and welfare of research participants are adequately protected. It is the responsibility of the Administrator and the REC as a whole to ensure that members and experts who review research protocols have no conflicting interest.

7.4 Determination of Conflict of Interest

- i. Disclosures shall be made by REC members or experts in writing to the REC Chairperson or verbally before the relevant protocol is discussed.
- ii. Disclosures shall be made by REC Chairperson to the REC Administrator.
- iii. The REC Chairperson, Vice-Chairperson or Administrator shall determine whether a conflicting interest exists. If the reviewer determines that any of the above four situations are met, the REC member will automatically be considered to have a conflicting interest.
- iv. At the time that research documents are submitted for REC review, the REC Administrator shall screen the documents to determine if any REC member is listed as key personnel for the study. If it is determined that any REC member has a COI, that member will not be assigned as a reviewer.

- v. Any REC 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 REC Chairperson or Administrator so that the protocol may be reassigned.
- vi. Upon receiving the REC agenda one week prior to its meeting, REC members are encouraged to notify the REC Administrator if they have any COI with studies on the agenda.
- vii. At the beginning of each REC meeting, the REC Chairperson shall ask REC members of possible COI for any of the full review items listed on the agenda.
- viii. REC members with a COI will not be counted toward the quorum in the review of that particular protocol.
- ix. The determination of whether or not a conflict existed will be recorded in the REC minutes.

7.5 *Recusal*

- i. REC members who have a COI related to any research protocol that the REC is about to consider 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 REC, and may not deliberate or vote on those protocols or related matters.
- ii. Unless requested by the REC to provide information at the meeting, the REC member or expert with a COI will be required to leave the room for the final discussion and vote.

7.6 *Meeting Minutes*

- i. During REC meetings, the deliberations shall be recorded in writing electronically. The minutes shall include a list of attendees, actions taken by the REC, the vote if any, on those actions, including the number of members voting for, against and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of issues and their resolution. The REC Administrator shall also include a summary of each considered protocol in the minutes.
- ii. The REC Administrator shall send a draft copy of the minutes to all REC members not later than two weeks to its next meeting.
- iii. All REC members shall review the minutes for accuracy and completeness. They may make recommendations to the minutes by communicating with the REC Administrator, or at the next REC meeting.
- iv. The Chairperson shall review the minutes for accuracy and completeness and will sign the minutes.
- v. The REC Administrator shall archive the official minutes with the meeting's agenda and all relevant attachments.

8.0 TYPES OF REVIEWS

8.1 *Definition - Minimal Risk*

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)).

8.2 Exempt Review

Exempt Research means that the research is not subject to a formal informed consent process or to continuing review by the REC. Research studies that may be considered for exemption are minimal risk research studies that conform to one or more of the following categories of research.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour unless:

- Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and 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.

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 directly or through identifiers linked to the subjects.

REC 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.

8.2.1 Determination

It is the responsibility of the UHAS-REC to make all determinations of exemption. Identification of research projects that qualify for exemption shall be made by the Chairperson or by one or more REC members designated by the Chairperson.

9.0 PROTOCOL AMENDMENT

This applies to previously approved study protocols which have been amended and submitted for approval. Amendments made to protocols shall not be implemented until reviewed and approved by the UHAS-REC.

9.1 Submission of an amended protocol

- i. The PI shall prepare the amended protocol and submit to the REC Administrator. The amended protocol shall include:
 - A letter stating the reasons for the amendment(s)
 - A completed protocol amendment form (available at the UHAS-REC website)
 - A list of the amendments and their location in the protocol/consent form(s)
 - The protocol/consent form(s) with tracked changes indicating the amendments effected
 - A clean version of the protocol/consent form(s) with the changes effected.
 - The amended protocol/consent form(s) shall be given a new version number and an effective date
- ii. At the Secretariat the Administrator shall:

- Notify the Chairperson of the submission.
 - Send the request for amendment and all related documents to the Chairperson within three (3) working days of receipt.
 - The Chairperson shall determine whether the protocol requires expedited or full Committee review
- iii. Protocol amendments which increase risk to study participants and therefore require full Committee review may include but is not limited to:
- Additional treatments or the deletion of treatments
 - Any changes in inclusion/exclusion criteria
 - Change in method of dosage formulation, such as, from oral route to intravenous route,
 - Significant change in the number of subjects (a change of 5% is considered significant).
 - Significant decrease or increase in dosage amount.
- iv. If an amendment is received just prior to the meeting of the Committee, the Chairperson may decide to review the amendment at a full Committee meeting, even though the amendment may qualify for expedited review.
- v. The Administrator shall note recommendations for changes to the protocol and/or informed consent requested by the Committee in the minutes and communicate the decision to the principal investigator in writing.
- vi. If the Committee does not approve the amendment(s), the notification to the investigator shall state the reason(s) for not approving the amendment.
- vii. If the Committee 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.

The Administrator shall archive all the submitted documents and correspondences throughout the process in the protocol file.

10.0 CONTINUING REVIEW

Principal Investigators shall submit review reports to the REC Secretariat for continuing review at least six weeks prior to the expiry of the protocol approval.

- i. The REC Chairperson and REC members are responsible for determining whether the research is reviewed annually, or more frequently as appropriate to the degree of risk.
- ii. The REC is also responsible for determining whether an independent data and safety monitoring Committee is required.
- iii. The principal investigator of the research is responsible for keeping the REC informed of significant findings that affect the risk/benefit ratio and thus the need for more frequent review.
- iv. The principal investigator is also responsible for following the continuing review procedures and deadlines as outlined in this SOP.

10.1 Determination of Frequency of Continuing Review

- i. At a research activity's initial review, the REC shall determine:

- How often it shall re-evaluate the research project. All research shall be reviewed at intervals appropriate to the degree of risk, but not less than once per year.
 - 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.
 - Whether these studies need verification from sources other than the principal investigator that no material changes in the research have occurred.
- ii. The principal investigator shall use the continuing review form to complete the annual review report. The report shall include all required elements, including the following:
 - Number and demographics of participants enrolled
 - Changes in principal and/or co-investigator(s)
 - A summary description of subject experiences
 - Any serious adverse events experienced
 - Numbers of and reasons for withdrawals from the research
 - The research results obtained thus far
 - A current risk-benefit assessment based on study results
 - And any new information since the REC's last review.
 - iii. If the investigator cannot provide any of the required information, s/he shall provide justification for the delay in the report, and a timetable for provision of the information.
 - iv. The principal investigator shall also submit a copy of the consent documents and procedures currently in use.
 - v. The principal investigator shall submit one hard copy of the continuing review report, with original signature.
 - vi. The principal investigator is also encouraged to submit an electronic/pdf copy of the review report via e-mail.
 - vii. Upon receipt of the continuing review report, the REC Administrator shall conduct a pre-REC review to ensure all the required elements are present. The REC Administrator shall work with the submitting principal investigator to ensure all elements are present before distribution of meeting items.
 - viii. The REC Administrator shall place the continuing review report on the next meeting's agenda.
 - ix. The REC Chairperson may elect to invite an independent or alternate reviewer to the meeting.
 - x. REC members shall consider and arrive at a consensus/vote on all continuing review reports in a full-Committee meeting.
 - xi. The risk/benefit ratio may change over time.
 - xii. The criteria the REC uses to approve or disapprove continuation of research are the same as the criteria for approval of an initial research protocol.
 - xiii. The REC 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 principal investigator have current REC approval.
 - xiv. After reassessment, the REC may require that the research be modified or halted.
 - xv. The REC may also impose special precautions or relax special requirements it had previously imposed on the research protocol.

- xvi. They 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, they shall require the principal investigator to notify the participants of these findings.
- xvii. The REC Administrator shall archive continuing review reports and supporting materials with the relevant meeting minutes.

10.2 *Timing of continuing review*

- i. If the REC has not reviewed and approved a research study by the study's current expiration date, REC approval has expired and research activities should stop. No new participants may be enrolled into the study
- ii. If the principal investigator cannot provide any of the required information, the principal investigator shall provide justification for the delay in the report, and a timetable for provision of the information. The principal investigator shall also submit a copy of the consent documents and procedures currently in use.

10.3 *Follow-Up Reviews*

The follow-up procedure should take the following into consideration:

Documents to be reviewed including but not limited to

- Progress reports, final reports
- Safety reports
- Audit reports, independent of the researcher and the sponsor
- Experiences of participants and potential participants (E.g. independent observation of the informed consent decision, independent surveys for participants' experiences)

Notification from the applicant with regards to suspension or premature termination or completion of the study.

The quorum requirements and communication procedure for follow-up, reviews, which may vary from the requirements and procedures for the initial review of the application;

- i. The intervals for follow-up reviews, which should be determined by the nature of the research project but should generally be at least once a year;
- ii. Circumstances that will trigger follow-up reviews, in addition to those that are regularly scheduled, include the following:
 - Any protocol amendment likely to affect the rights, safety and or well-being of the research participants or the conduct of the study;
 - Serious unexpected adverse events related to the conduct of the study or study product, Any event or new information that may affect the benefit/risk of harm involved in the study;
 - Decision made by the DSMB or other monitoring or regulatory authorities to suspend the study in whole or in part

A decision resulting from a follow-up review should be issued and communicated to the applicant, indicating either that the original decision is still valid or that there has been a modification, suspension, or withdrawal of the REC's original decision.

11.0 DOCUMENTATION AND ARCHIVING

All documentation and communication of the REC should be dated, filed and archived according to the committee's policies. A statement is required defining the access and retrieval procedure (including authorized persons) for the various documents, files, and archives.

Documents shall be archived for a minimum period of 3 years following the completions of a study.

12.0 ARCHIVING OF COMMITTEE RELATED DOCUMENTS

12.1 *Committee-related documents*

Committee-related documents that should be filed and archived include, but are not limited to:

- Any document formally establishing the REC
- The REC SOPs
- The published guidelines for submission established by the REC
- Annual reports summarizing REC activities. Curricula vitae of all REC members
- Record of all income and expenses, including allowances and reimbursements made to the secretariat and REC members and for what purposes
- Agendas of the REC meetings
- Minutes of the REC meetings
- Regulatory texts used by the REC

12.2 *Project-related documents*

All documents and materials related to the review of specific projects should be filed. Committee procedures should specify length of time documents must be archived – for example, with studies under ICH GCP, the documents are archived for a minimum period of 3 years following completion of the study.

These include, but are not limited to:

- One copy of all materials submitted by an applicant;
- Any correspondence by the REC with applicants or concerned parties regarding applications, decisions, and follow-up;
- A copy of initial and follow-up decisions and any advice or requirements sent to an applicant;
- All written documentation received during the follow-up;
- The notification of the completion, premature suspension, or premature termination of a study;
- The final summary or final report of the study

13.0. TRANSLATION OF THE CONSENT DOCUMENT

- i. 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 judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research
 - ii. All documents translated from English to another language should receive REC review and approval before use, to ensure that the rights and welfare of research participants are adequately protected.
 - iii. The Committee shall 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) of the informed consent information in a language understandable to the non-English speaker.
 - iv. The Committee shall review and approve any translated documents that were previously REC approved versions in English.
 - v. The translated document is translated back into English. The person providing the back translation must be different from the person providing the original translation.
 - vi. The REC may invite an expert to review the translated document to determine its cultural appropriateness.
 - vii. 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.

At a minimum, the following signatures are required:

- When a potential participant has understood and has agreed to participate in the research, he/she shall sign the consent form.
- For persons unable to sign, they shall be required to thumbprint. In such instances, a witness shall countersign the form.

14.0 MONITORING OF ON-GOING RESEARCH

- i. The UHAS-REC shall perform or designate qualified agent(s) to perform on its behalf, on-site inspection of the research projects it has approved.
- i. The Administrator in consultation with the Chairperson shall initiate an on-site monitoring of a study project.
- ii. The approved study to be monitored shall be selected based on the following criteria:
 - The level of risk
 - Frequency of reports of serious adverse events
 - Failure to submit progress report
- iii. The Committee shall notify the PI in writing within one week about plans of the visit.
- iv. The Committee may carry out an unannounced monitoring visit if:
 - The PI does not submit a progress report as per the SOPs after two reminders.
 - The PI prolongs study completion beyond the approved time frame.
 - The PI is suspected to have changed the objectives and design of the study without prior approval from the Committee.

- v. The Administrator shall make the necessary arrangements and logistics for the visit.
- vi. The Administrator shall ensure that the monitoring team has all the necessary information to carry out the audit.
- vii. He/she shall be part of the team that carries out the monitoring.
- viii. The monitoring team shall:
 - Review the informed consent document to make sure that the study is using the most recent approved version.
 - Observe the informed consent process, if possible.
 - Review the data collection instruments to make sure that the study is using the most recently approved version.
 - Observe enrolment/recruitment procedures to make sure that they are in accordance with the most recently approved protocol.
 - Observe if there are any protocol violations or deviations.
 - Observe if safety procedures are being implemented
 - Observe procedures to ensure confidentiality of study information
 - Find out if there are SAEs that are not being reported to the Committee.
- ix. At the end of the monitoring, the team shall:
 - Hold a debriefing before departure
 - Write a report within two weeks of the monitoring visit
 - Forward a copy of the report to the Chairperson and the PI of the study.
 - The team shall brief the full Committee at a scheduled meeting on the visit.
 - The REC Administrator shall archive the monitoring report in the study file.

15.0 STUDY CLOSURE AND RE-OPEN

A study is eligible for closure if it meets all of the following criteria:

- i. The PI has completed enrollment and data collection
- ii. The PI no longer has any contacts or interactions with the subjects, including long-term follow up
- iii. Analysis of identifiable data is complete and, if a manuscript or presentation is planned, there is no possibility of further data analysis requests (i.e., acceptance of publication or presentation).
- iv. The principal investigator (PI) shall notify the REC Administrator when a research study is closed, either temporarily or permanently.
- v. The Research Ethics Committee (REC) shall close a study if it does not approve the study by its expiration date.

15.1 Closure Initiated by the PI

- i. The PI shall promptly notify the REC, in writing, when study activities are terminated or suspended by the investigator for any reason, including normal and anticipated study closure.
- ii. The PI shall submit both a completed study closure form and a summary of the study findings at the time of the closure.
- iii. The REC Chairperson or his/her designee may determine that the Research Ethics Committee (REC) closes a study if its ethical approval expires. However, before a study is closed by the REC, the Administrator shall make every effort to contact the PI to verbally notify him/her that the study may be closed. If the REC closes the study, the PI will be notified immediately.

- iv. The REC Administrator shall forward a study closure letter to the PI, notifying him/her that recruitment/enrolment is temporarily closed and the treatment/intervention with previously enrolled participants/patients must stop. If the principal investigator wishes to continue to treat previously enrolled participants/patients, he/she needs to contact the Chairperson of the Committee immediately to provide rationale for the continuation of this treatment/intervention.
- v. The REC shall address on a case-by-case basis those rare instances where failure to enroll would seriously jeopardize the safety or well-being of an individual prospective participant.
- vi. The REC may also suspend or terminate a study based on review of unanticipated problems involving risks, study participant complaints/concerns requiring evaluation, or serious or continued non-compliance of REC approved procedures. This closure is final, the file will be closed and all the relevant files archived.

15.2 Closure Initiated by the REC

- i. The REC may close a study if its ethical approval expires. However, before the study is closed, the Administrator shall make every effort to contact the PI to verbally notify him/her. If the REC closes the study, the PI will be notified immediately.
- ii. The REC Administrator shall forward a study closure letter to the PI, notifying him/her that recruitment/enrolment is temporarily closed and the treatment/intervention with previously enrolled participants/patients must stop. If the principal investigator wishes to continue to treat previously enrolled participants/patients, he/she shall contact the Chairperson of the Committee immediately to provide rationale for the continuation of this treatment/intervention.
- iii. The REC shall address on a case-by-case basis those rare instances where failure to enroll would seriously jeopardize the safety or well-being of an individual prospective participant.
- iv. The REC may also suspend or terminate a study based on review of unanticipated problems involving risks, study participant complaints/concerns requiring evaluation, or serious or continued non-compliance of REC approved procedures.

15.3 Sponsor/PI Requests to Access Patients' Records of a Closed REC File

- i. If a sponsor/PI requests to review patient's medical records of a closed REC file, for audit purposes, the REC file will not need to be re-activated. A memo documenting this request shall be added to the REC file.
- ii. The REC Administrator shall retrieve the applicable file(s) from storage and place a memo in it stating whom, when and what will be reviewed.
- iii. If the sponsor /PI's request is to review patients records to collect new data/information, the file must be re-activated.

16.0. REVIEW OF FINAL REPORTS

- i. The final report is an obligatory review of each PI's activities. It shall be carried out when the last participant has completed all visits and all adverse experiences have been brought to appropriate resolution.
- ii. The PI shall submit a completed final report form (Available at the REC website)
- iii. The PI shall also submit a summary of the activities of the study to date and any significant findings so far.

- iv. The Administrator shall read the submitted report and give a briefing to the Chairperson before making copies and distributing it to all Committee members.
- v. Each Committee member shall review a copy of the final report before deliberating on it. If appropriate to the discussions, the Committee may call for consensus on whether to request further information or to take other action with the PI before summarizing what action to be taken.
- vi. After the Committee meeting, the Administrator shall notify the PI of the decision taken. If no action is required from the PI, the Administrator shall file the final report and consider the study closed.

17.0. USE OF DATA SAFETY MONITORING BOARD (DSMB)

- i. In larger studies or trials, the REC may require a DSMB to be formed to keep it up-to-date with the balance between risks and benefits.
- ii. The primary responsibility of a DSMB is to safeguard human subjects by analysing accumulating data relevant to the risks and benefits on regular basis. Especially in long-term trials, the DSMB reviews data periodically to assess effectiveness and toxicity, and to decide if and when the data are sufficiently favorable to one treatment that the study should be discontinued. The DSMB must also decide whether adverse effects are serious enough to warrant termination of the study.

18. 0 SAFETY/SERIOUS ADVERSE EVENTS (SAES) REPORTING

Unanticipated risks are sometimes discovered during the course of a study that may impact on the risk/benefit ratio.

- i. The PI shall promptly report SAEs within 48 hours to the committee for its review to ensure adequate protection and welfare of the study participants.
- ii. The primary responsibility of the UHAS-REC is to review and address SAE and unexpected events involving risks to subjects or others as well as ethics complaints.
- iii. The Administrator shall be responsible for first screening and assessing the reports and seeing whether they need a review by a full Committee, the Chairperson, other qualified Committee member or an expert.

The criteria of the review shall be as follows:

- 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 Committee should review the report at a convened meeting.
- If assessment of adverse experience is possibly caused by, or probably caused by the investigational drug, the full Committee should add the report to the agenda for review at a convened meeting.
- If an adverse experience/investigational new drug safety report has previously been seen by the full Committee is being resubmitted by another investigator in the same study (as part of a multi- Centre study), this notification shall not require full Committee review. It shall instead be reviewed by the Chairperson or other qualified member of the Committee.

If the full Committee meets to discuss the report, it shall determine by consensus or vote on whether to:

- Request an amendment to the protocol or consent process
- Request further information
- Suspend or terminate the study

If any of the above actions is taken, the Administrator shall notify the PI of the action taken. The Administrator shall draft a formal letter signed by the Chairperson to the PI notifying him/her of the action he/she should take according to the Committee's decision.

19.0 PROTOCOL DEVIATIONS

- i. A protocol deviation is a minor or administrative departure from the protocol procedures approved by the REC that was made by the PI without prior REC approval. Eligibility exceptions are considered changes in research that require REC review and approval before a subject who does not meet the approved protocol inclusion/exclusion criteria may be enrolled.
- ii. Protocol deviations that constitute unanticipated problems involving risks require prompt reporting to the REC:
 - **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 REC must be notified as soon as possible, but in no event later than 3 days after the emergency occurs
 - **Major, non-emergent deviations without prior approval:** A planned deviation that is non-emergent and represents a major change in the protocol as approved by the REC must be submitted as a change in research. The REC must approve the request before the proposed change is implemented. If a major, non-emergent deviation occurs without prior REC approval the event is considered non-compliance. A PI's failure to report promptly any major, non-emergent deviation for which he/she did not obtain prior approval is itself an incident of non-compliance.
 - **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 UHAS-REC 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.
- iii. Reporting Requirements:
All protocol deviations should be reported immediately, if they represent a significant alteration in the approved protocol and/or if it affects the safety or welfare of the subject, otherwise, the reports should be made during continuing review.
- iv. Protocol deviations that should be reported to the REC include the following:
 - Changes to the research protocol initiated by the PI prior to obtaining REC approval (e.g. to eliminate apparent immediate hazards to subjects).

- Modification of inclusion or exclusion criteria to mitigate newly identified risks
 - Implementation of additional procedures for monitoring subjects
 - Suspension of enrollment of new subjects
 - Suspension of research procedures in currently enrolled subjects
 - Modification of informed consent documents to include a description of newly recognized risks
 - Provision of additional information about newly recognized risks to previously enrolled subjects
 - Deviations that result in serious breach of confidentiality or privacy.
 - Specific examples of potentially reportable deviations (i.e., if they place subjects at a greater risk)
 - Informed consent improperly obtained or not obtained
 - Subject enrolled without meeting the eligibility criteria and without prior sponsor approval
 - Study drug or dose not administered per protocol and that increases the risk of harm to the subject
 - Unauthorized removal of personal health records offsite, or patient names showing on records that are submitted to the sponsor.
- v. Protocol Deviations that lead to an SAE should be reported within 48 hours, otherwise within 7 working days.

20.0 PROTOCOL VIOLATIONS

Planned changes to the REC-approved protocol, i.e., protocol deviations must be submitted as formal protocol amendments to the REC and must be approved prior to initiation or implementation of the change. Any protocol deviation that is not approved by the REC prior to initiation is a protocol violation and must be reported to the REC as outlined below.

20.1 Major Violation

A violation that may impact on subject safety, affect the integrity of study data and/or affect subject's willingness to participate in the study. e.g.

- 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 REC to obtain consent
- iii. Enrollment of a subject who did not meet all inclusion/exclusion criteria
- iv. Performing study procedure not approved by the REC
- v. Failure to report serious adverse event to the REC 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/or affect subject's willingness to participate in the study. e.g.

- 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
 - missing subject signature
 - missing investigator signature
 - copy not given to the person signing the form
 - someone other than the subject dated 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
 - Study procedure conducted out of sequence
 - Omitting an approved portion of the protocol
 - Failure to perform a required laboratory test
 - Missing laboratory results
 - Enrolment of ineligible subject (e.g., subject's age was 6 months above age limit)
 - Study visit conducted outside of required timeframe
- vii. Failure of subject to return study medication
- viii. Over-enrolment
- ix. Enrolment of subjects after REC-approval of study expired
- x. Failure to submit continuing review application to the REC before study expiration.

20.3 Reporting Requirements

All major protocol violations must be reported to the REC within seven (7) working days of discovery.

Minor violations are to be reported at continuing review.

It is the responsibility of the PI to determine whether a violation is major or minor and to ensure proper reporting to the REC.

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, report during continuing review.

In reporting a protocol deviation or violation to the UHAS-REC;

- i. The PI shall complete a protocol deviation/violation form (available at the UHAS-REC office/website) and provide a summary of the reasons for the deviation.
- ii. The PI shall also state steps put in place to forestall the future occurrence of such a deviation/violation.

21.0 DOCUMENTATION AND ARCHIVING

- i. All documentation and communication done by the REC shall be dated, filed, and archived.
- ii. Documents should be archived for a minimum period of 3 to 5 years following the closure of a study.

- iii. Documents that should be filed and archived include but are not limited to:
- Written standard operating procedures of the REC
 - Updated lists of REC members
 - CVs of members
 - Agenda of REC meetings
 - Minutes of REC meetings with names of members present, date of meeting, decisions made, and any other details
 - One copy of all materials submitted by each and every applicant
 - Correspondence between REC members and applicants or concerned parties regarding application, decision and follow up
 - Copy of the decision and any advice or requirements sent to each and every applicant
 - Progress reports received from researchers as per REC requirements
 - Serious Adverse Event reports submitted by researchers
 - Final reports from researchers
 - Oversight visit reports by REC members

21.1 Procedure

The Procedure's section shall be written in immediate future tense using active verbs. It shall be written so that a reader unfamiliar with the procedure would be able to duplicate the procedure accurately in proper time sequence by following the document.

21.2 Distribution and Archiving

The REC Administrator shall distribute the SOP to all REC members, archive the electronic copy and the paper original, and update the indexed list of SOPs.

All requests for extra copies may be made to and fulfilled by the REC Administrator.

22.0 SOP REVISION

If the Committee wishes to revise or update an SOP, it shall request an electronic copy of the document from the REC Administrator, or may request minor changes be made directly by the REC Administrator.

22.1 Annual Review

- i. The SOP will be evaluated for accuracy and timeliness in an annual review. The REC Administrator will alert the Committee of an annual review requirement.
- ii. The Committee or an assigned reviewer will ensure that the SOP reflects the most current outline of procedures.
- iii. If the document does not need revision, the author will return the document to the REC Administrator for recording and filing.

REFERENCES

- ❖ 45 Code of Federal Regulations 46.115 REC Records, .108.b REC Functions and Operations. 21CFR56.115 IRB Records
- ❖ CIOMS guidelines
- ❖ Declaration of Helsinki
- ❖ ICH guidelines
- ❖ NHRC SOPs
- ❖ The Belmont report
- ❖ WHO Guidelines
- ❖ GHS Ethical Review Committee SOP
- ❖ NMIMR IRB SOP
- ❖ University of Ghana College of Health Sciences EPRC SOP