

STANDARD OPERATING PROCEDURES

KINTAMPO HEALTH RESEARCH CENTRE INSTITUTIONAL ETHICS COMMITTEE (KHRCIEC)

REVISED

**Kintampo Health Research Centre Institutional Ethics Committee (KHRCIEC)
SOP**

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Mission Statement

The Kintampo Health Research Centre (KHRC); as an important unit within the Ministry of Health/Ghana Health Service umbrella, has the responsibility of contributing to the improvement of the health status of people in Ghana particularly the middle sector through appropriate research activities.

As an independent representative body, the Institutional Ethics Committee (IEC) is set up to review, evaluate and decide on the ethical merits of KHRC and or any research protocol(s) before it. The IEC is committed to ensuring and safeguarding the rights, dignity and safety of participants and communities in Kintampo and or research activities reviewed by the Committee.

Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting human participants. The ethics review of research protocols with human participants has been emphasized in various international guidelines and regulations governing research. Notable among these guidelines include the Council for International Organizations for Medical Sciences (CIOMS) guidelines, Belmont Report, Declaration of Helsinki and the International Council on Harmonization (ICH) Good Clinical Practice guidelines.

The KHRC IEC takes cognizance of these international guidelines and local/cultural norms in Ghana (specifically Kintampo) in the review of various research activities involving the use of human participants, ranging from local data-gathering protocols to clinical trials and any other type outlined in the Declaration of Helsinki, ICH Good Clinical Practices guidelines, Belmont Report, CIOMS guidelines and any other applicable regulations and guidelines. In pursuance of the ultimate goal of the IEC (protection of research participants), the committee shall be guided by these SOPs in the review of research protocols submitted to it for consideration.

Terms of Reference

The KHRC IEC shall operate within the following terms and references:

- I. The IEC shall review research protocols submitted to it within a stipulated time and document its decision in writing to applicant(s), clearly identifying the study, documents reviewed and dates for the following:
 - Approval for commencement of study
 - Modifications required before approval
 - Disapproval
 - Termination/suspension of any prior approval
- II. The IEC shall work to safeguard the dignity, rights, safety and wellbeing of study participants and communities. Special attention shall be paid to vulnerable participants.
- III. The IEC shall react to any allegations of misconduct in research involving humans carried out by researchers within its jurisdiction.
- IV. The IEC shall advice KHRC on all matters pertaining to the ethics of research involving human participants.
- V. The IEC may invite investigator(s) to briefly (5-10 minutes) present their studies but investigator(s) shall not participate in deliberations or in voting process of meetings.
- VI. The IEC shall obtain the following documents from investigators:
 - Protocol(s) and/or amendment(s)
 - Scientific review committee approval letter from KHRC
 - Approval/review decision/comments from other IRBs/committees
 - Written informed consent forms and information sheets
 - Subject recruitment procedures
 - Data collections tools (questionnaires, FGD guides, IDI guides)
 - Available safety information on study drugs/medical devices
 - Investigators Brochure
 - Information on benefits available to participants
 - Material Transfer Agreements (MTAs)
 - Research budget

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- Curriculum vitae of research team members
 - Time frame for research
 - Dissemination plan
 - Contact details of investigators and or sponsors
 - And any other document relevant for review process
- VII.** The IEC shall consider suitability of investigator(s) for proposed research considering relevant qualification, training and experience, as documented by current curriculum vitae and/or by any other relevant documentation.
- VIII.** The IEC may request additional information when, at its discretion, the additional information would assist in taking a decision on a protocol.
- IX.** The IEC shall review both amount and type of benefit(s) to participants to ensure coercion or undue inducement to participants does not occur.
- X.** The IEC shall review protocol(s) based on ethical and scientific merits free from bias or external influence.
- XI.** The IEC shall not be involved in administration, policy direction or other administrative issues of KHRC.
- XII.** To assist investigators in protocol submissions, the following will be made available to them by the IEC secretariat;

Institutional Materials

- IEC standard operating procedures
- Meeting schedule
- Protocol submission form or requirements
- Sample Consent form and consent form checklist
- Sample progress/final report forms or requirements

Reference Materials

- The Public Health Act (PHA) of Ghana, 2012, Act 851
- The Children’s Act of Ghana, 1998, Act 560 (Protecting the rights of children in Ghana)
- Data Protection Act of Ghana, 2012, Act 843.
- Policy on protection of Human Participants “Common rule Policy”
- Code of federal regulations: 45 CFR Part 46 DHHS, NIH
- The Belmont Report

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- CIOMS guidelines
- The Declaration of Helsinki
- Other relevant materials on human subject protection including customary laws in Ghana.

1.0 SOP # 01: CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1.1 *Appointments of Members*

- 1.1.1 Management of KHRC in consultation with IEC secretariat shall be responsible for making appointments of committee members.
- 1.1.2 Members shall be selected in their personal capacities, based on their interest, ethical and or scientific expertise, as well as their commitment and willingness to volunteer the necessary time and effort for the committee's work.
- 1.1.3 Appointments should consider age and gender distribution, and relevant but diverse professional representation.
- 1.1.4 The appointing authority shall write an appointment letter to the prospective member inviting him/her to be a member of the IEC.
- 1.1.5 Membership shall be effective upon receipt of appointing authority letter and after signing privacy-confidentiality and conflict of interest forms
- 1.1.6 Members shall be appointed for a period stipulated in tenure section
- 1.1.7 Membership may be renewed up to two consecutive terms as stated in the tenure of office.
- 1.1.8 The Head/Director of the Kintampo Health Research Centre shall be a non-voting member on the IEC.

1.2 *Composition of the Committee*

- 1.2.1 The IEC shall be multidisciplinary and multi-sectoral in composition, including persons with relevant but diverse scientific expertise,

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balanced age and gender distribution, who have the qualifications and experience to review and evaluate non-scientific, scientific and medical ethics aspects of research protocol.

1.2.2 The IEC shall be composed of selected personalities from five or more of the following departments and or local academic institutions within the region and specifically in the Kintampo North municipality and South district subject to periodic review:

- 1.2.2.1 Representative(s) from academia
- 1.2.2.2 Head of management of KHRC (Director)
- 1.2.2.3 Representative(s) from Kintampo North municipal or Kintampo South District Hospital
- 1.2.2.4 Representative(s) from civil society (civic education)
- 1.2.2.5 Representative(s) from traditional authority/council
- 1.2.2.6 Representative(s) from regional or municipal health directorate or Kintampo North Municipal or Kintampo South District Assembly
- 1.2.2.7 KHRC Staff (but number should be less than non-KHRC members by at least 1 person) - administrator(s) excluded in count.
- 1.2.2.8 The IEC shall consist of a reasonable number of members who collectively have the qualification and experience to review and evaluate the science, medical aspect and ethics of research protocols.
- 1.2.2.9 Gender equity will be adhered to in the IEC composition
- 1.2.2.10 One member of the IEC shall be a clinical scientist, one a non-scientist and one a community representative

1.3 *Conditions of appointment*

1.3.1 Willingness to publicize identity, name, profession and affiliation to the committee.

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- 1.3.2 Willingness to sign a confidentiality agreement at the start of the term office
- 1.3.3 Willingness to abide by confidential agreement regarding meeting deliberations, applications, protocol submissions, information on research participants and related matters which they have had the privilege to access as a result of being members of the committee.
- 1.3.4 Protects privacy and confidentiality of all parties whose information may be disclosed to the committee in the course of its work.
- 1.3.5 Willingness to disclose in writing any interest or involvement – financial, professional, or otherwise – in a project or proposal under consideration.

1.4 *Term of office (tenure)*

- 1.4.1 Membership shall be a period of three (3) years
- 1.4.2 Membership may be renewed twice; however, at least one-third of the old members should be retained at every point in time.
- 1.4.3 Maximum of three (3) terms is allowed (9 years) subject to competence, meeting attendance records and willingness to serve
- 1.4.4 For continuity and smooth running of the IEC office, hired/contracted IEC administrator/coordinator/secretary shall serve a maximum of five (5) terms, which translates to a maximum of fifteen (15) years.
- 1.4.5 For permanently employed administrators, tenure is not limited provided they are still employed
- 1.4.6 Limit of tenure of IEC Administrators/Coordinators/Secretaries shall be reviewed every five years to reduce it if availability of personnel trained in Health Research Ethics employed at KHRC improves.

1.5 *Replacement of membership*

- 1.5.1 KHRC shall request for a replacement of any member under the following circumstances:

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- 1.5.1.1 Protracted illness of a member, which does not permit him/her to participate in the deliberations of the committee and if after consultation with the member, he/she would not be able to continue with Committee activities.
- 1.5.1.2 Persistent absenteeism of a member without reasonable cause.
- 1.5.1.3 Voluntary withdrawal (resignation) by a member.
- 1.5.1.4 End of tenure (9 years).

1.6 *Termination of membership*

- 1.6.1 Membership may be terminated voluntarily by a member who should write a resignation letter to the appointing authority through the IEC chairperson
- 1.6.2 The chairperson may resign by sending his/her resignation letter to the appointing authority after duly informing the committee in a meeting
- 1.6.3 Voluntary resignation shall require a prior notice of at least one month
- 1.6.4 Membership should be terminated by the appointing authority on the advice of the IEC if a member would be absent more than one year
- 1.6.5 Membership should be terminated by the appointing authority upon advice by the IEC if a member has been absent from three consecutive meetings without apologies
- 1.6.6 Membership could be terminated by the appointing authority upon advice by the IEC if a member has been absent from six consecutive meetings with apologies.
- 1.6.7 Membership shall be terminated by the appointing authority for misconduct that tarnishes the credibility of the IEC as determined and advised by KHRC.

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- 1.6.8 Membership shall be terminated if a member is convicted by a court of law for a criminal offence
- 1.6.9 Membership should be terminated by the appointing authority in consultation with the IEC if a member is suffering from chronic incapacitating illness.
- 1.6.10 Membership shall automatically terminate when a member dies

1.7 *Dissolving the committee*

- 1.7.1 At any point in time, should KHRC cease to exist, the committee is automatically dissolved.

1.8 *Ethical basis*

- 1.8.1 The committee recognizes that protocols it reviews may also be reviewed by other ethics committees prior to submission to this committee or their implementation in specific localities.
- 1.8.2 In evaluating protocols, the committee is aware of the diversity of laws, cultures and practices in various communities in Ghana and the ethical issues pertaining to research and medical practices.
- 1.8.3 The committee shall be guided in its reflections, advices, and decisions by the ethical principles expressed in the *Declaration of Helsinki (1964 and subsequent revisions)*
- 1.8.4 The committee shall be guided by International Ethical Guidelines for Biomedical Research Involving Human Participants (CIOMS), Belmont Report, and *European Convention on Human Rights and Biomedicine*.
- 1.8.5 The committee has established SOPs based on operational guidelines for ethics committees that review biomedical research (WHO) and the ICH guidelines for Good Clinical Practices.
- 1.8.6 The committee shall fulfil the requirements for international assurances and is established and functions in accordance with national laws.

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- 1.8.7 The committee shall review both the amount and type of benefit to participants to ensure that such benefits do not present problems of coercion or undue influence on study participants.
- 1.8.8 The committee members and consultant reviewers shall be provided by the secretariat all relevant SOPs to guide them in the review process of research protocols
- 1.8.9 Any member who has any vested interest in a protocol submitted to the committee for review shall be excused in that protocol review (deliberations)

2.0 SOP # 02: CONFIDENTIALITY/CONFLICT OF INTEREST

2.1 Purpose

- 2.1.1 This procedure (SOP) is to provide a form of confidentiality/conflict of interest agreement for committee members and/consultants.
- 2.1.2 This SOP covers the agreement on both confidentiality and conflict of interest, concerning activities and information of the Kintampo Health Research Centre Institutional Ethics Committee (KHRCIEC).
- 2.1.3 It is the responsibility of all newly appointed committee members and consultant reviewers to read, understand, accept and sign the agreement stated on the confidentiality/conflict of interest form (Form # 01) before beginning their task(s) with the KHRCIEC in the interest of protecting the rights of research participants.

2.2 Detailed instructions

- 2.2.1.1 Newly appointed member(s) or consultant reviewer(s) shall:
- 2.2.1.2 Obtain copies of the agreement form (Form # 01) from the Secretariat
- 2.2.1.3 Read through content of the form carefully and complete
- 2.2.1.4 Ask questions, if any and the secretariat shall explain or clarify the context
- 2.2.1.5 Sign and date both copies at the undersigned signature section and give the forms back to the IEC administrator to sign and date
- 2.2.1.6 Keep a copy of signed form for their personal records.
- 2.2.2 The administrator shall keep a copy of the signed agreement as the committee's records in a confidentiality/conflict of interest agreement file.

3.0 SOP # 03: ADMINISTRATION/FUNCTIONS OF IEC

This SOP describes responsibilities of management of KHRC, administration/ or office bearers in ethics secretariat and their functions. It also describes the responsibilities of the Chairperson, vice, committee members and consultant reviewer(s).

3.1 *Responsibilities of Management of KHRC*

- 3.1.1 KHRC shall prepare and provide a statement of assurance guiding the establishment of the committee.
- 3.1.2 KHRC shall ensure the provision of necessary logistic and financial support for operations of the committee.
- 3.1.3 Head of management in KHRC (non-voting member) shall take part in all discussions of the committee but shall not vote on decisions made by the committee on reviewed protocols
- 3.1.4 If s/he has an interest in a particular protocol, s/he shall be excused in review process of that protocol.

3.2 *Officers/ secretariat of the committee*

- 3.2.1 Officers/secretariat of the committee shall comprise the Chairperson, Vice Chairpersons and administrators (Administrator and Assistant administrator).
- 3.2.2 Chairperson shall be elected from among appointed members of the committee for each specific term
- 3.2.3 Administrators shall be employees of KHRC.
- 3.2.4 Chairperson shall be a respected person in the community, who has the qualifications of medical or social sciences, is concerned about human rights and ethical issues and is well informed in regulations relevant to the use of human participants in research.
- 3.2.5 The committee shall have a permanent secretariat at KHRC manned by the committee administrators

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3.3 *Responsibilities of the Secretariat*

- 3.3.1 Organize effective and efficient tracking procedures for received protocols.
- 3.3.2 Prepare, maintain, and distribute study protocols for members.
- 3.3.3 Organize regular committee meetings as per SOP timelines.
- 3.3.4 Prepare, distribute and store meeting agenda and minutes.
- 3.3.5 Maintain the committee's documentation and archive system properly.
- 3.3.6 Communicate effectively with members and investigators.
- 3.3.7 Facilitate trainings for personnel and committee members.
- 3.3.8 Recommend preparation, revision and distribution of SOPs and guidelines.
- 3.3.9 Provide needed administrative support for the committee.
- 3.3.10 Provide updates on relevant and current issues related to ethics in health research, as well as relevant current literature to committee members.

3.4 *Responsibilities of Administrator(s)*

- 3.4.1 Administrator(s) shall be responsible for oversight of committee secretariat.
- 3.4.2 Administrator(s) shall be responsible for pre-review of submitted protocols to the committee.
- 3.4.3 Administrators shall undertake all administrative procedures in providing training and educational programs to new and continuing committee members, and the scientific community in Kintampo/KHRC.
- 3.4.4 Administrator(s) shall support the Chair and vice in preparing and providing a statement of assurance when required that guides the establishment of the committee.
- 3.4.5 Administrator(s) shall design and disseminate templates for committee submission documents, including research protocols,

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informed consent materials, agreements, progress and final reports.

- 3.4.6 Administrator(s) shall design and maintain a system for collecting and filing all committee documents, including meeting minutes, member qualifications, protocol submission versions, and deviations from approved protocols.
- 3.4.7 Administrator(s) shall assist the institution to recruit new committee members
- 3.4.8 Administrators shall prepare and submit annual committee operational budget and plan to KHRC management in consultation with the Chair.
- 3.4.9 Administrators shall accept, verify, duplicate and distribute all submitted items to members for committee review in time.
- 3.4.10 Administrators shall create and distribute meeting agendas, and arrange meeting logistics and take minutes
- 3.4.11 Administrators shall advise submitting investigators on preparing and submitting protocols for review according to relevant SOPs.
- 3.4.12 Administrators shall correspond with all submitting researchers at all times throughout the submission and review process, while remaining independent of researcher's protocol operations. They shall properly distribute and keep files of all correspondences.
- 3.4.13 Administrators shall assist the chair to conduct committee meetings and shall continually study and update staff about committee operational regulations.
- 3.4.14 Administrators shall be available for and attend any outside investigations or audits of the committee and shall comply with requests during an investigation or audit.
- 3.4.15 Administrator(s) shall carry out any other duties assigned to them by the Chair

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3.5 *Election and responsibilities of Chairperson*

- 3.5.1 The Chairperson shall be a respected person in the community, who has the required qualifications (scientific background preferable), is concerned about human rights and ethical issues and is well-informed in regulations relevant to the use of human participants in research.
- 3.5.2 In order to enhance independence of the committee, the chairperson should not be affiliated with the institution where the IEC is based
- 3.5.3 The Chair shall be appointed for a three-year term, renewable for two consecutive three-year terms.

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3.6 *Responsibilities of chairperson*

- 3.6.1 Chair committee meetings in accordance with all regulations.
- 3.6.2 Prepare and provide a statement of assurance when required by the regulations guiding the establishment of the committee.
- 3.6.3 Facilitate provision of training and educational programs to new and continuing committee members and the scientific community of Kintampo. The training shall include programs about the basic principles of human subject protection, current literature, regulations and guidelines ethics committee.
- 3.6.4 Review and accept revisions that were made as per the committee recommendation pending protocol approval.
- 3.6.5 Determine submissions that could be exempted from review, and notify the committee and the submitting investigator of such exemptions.
- 3.6.6 Arrange expedited review of research that meets the expedited review criteria.
- 3.6.7 Assign responsibilities and duties to any other member in his or her absence and assign responsibilities to other members of the committee.
- 3.6.8 Supervise the Administrator and ensure s/he is performing his/her task dutifully.
- 3.6.9 Sign all IEC official documents such as approval certificates.

3.7 *Election and Responsibilities of Vice Chair*

- 3.7.1 *Two vice Chairpersons (1st and 2nd vice Chairpersons) shall be elected to assist the Chairperson in Committee activities.*
- 3.7.2 *The vice Chairpersons shall be voting members and must have served on the Committee for more than 6 months.*
- 3.7.3 *A vice Chairperson shall be appointed for a three year term, renewable for two consecutive three year terms.*

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- 3.7.4 The first and second Vice chairpersons should chair meetings and sign IEC official documents when the chairperson is not available
- 3.7.5 The Vice chairpersons may sign IEC official documents such as approval certificates if the chairperson is not available
- 3.7.6 In the absence of both the chairperson and Vice chairpersons, the IEC members should select an acting chairperson to chair the current meeting provided a quorum is satisfied.
- 3.7.7 The selected acting chairperson should sign minutes of previous meeting confirmed during his/her chairpersonship.
- 3.7.8 Acting chairperson should not have authority to sign IEC official documents but may sign minutes confirmed during his/her chairpersonship.
- 3.7.9 The process of resignation should be the same as that for the chairperson.

3.8 *Responsibilities of committee member(s)*

- 3.8.1 Review, discuss and consider research protocols submitted for evaluation to safeguard the rights and well-being of study participants.
- 3.8.2 Review progress reports and monitor ongoing studies as appropriate. Evaluate final reports and outcomes.
- 3.8.3 Support the secretariat in the discharge of their duties when called upon.
- 3.8.4 Maintain confidentiality of documents and deliberations of the committee meetings.
- 3.8.5 Declare conflict of interest.
- 3.8.6 Participate in continuing education activities in biomedical ethics and research.
- 3.8.7 Undertake duties assigned to them by the Chair.
- 3.8.8 Attend meetings regularly and participate actively during deliberations.

4.0 SOP # 04: MEETINGS OF THE COMMITTEE

4.1 Meeting schedule and agenda distribution

- 4.1.1 Except for unavoidable circumstances, the KHRC IEC shall meet once a month at 2:00 pm (14:00 GMT) within the KHRC premises, provided materials have been submitted for review.
- 4.1.2 In a case where the above is not possible or in expedited review circumstances, Chairperson shall provide an alternate meeting time and date.
- 4.1.3 The Chair shall lead the meeting. In the absence of the Chair, the first or second Vice-Chairperson shall lead the meeting.
- 4.1.4 In the absence of both the chair and vice-chairs, a voting member shall be nominated to lead the meeting by members present.
- 4.1.5 The IEC Administrators shall notify all IEC members of an upcoming meeting at least one week in advance by at least one of the following means: electronic mail, phone call, and fax or courier mail/messenger delivery.
- 4.1.6 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, etc.
- 4.1.7 In the case where administrators are unsuccessful in routing the materials to the IEC members, they shall at the least notify the member(s) of the occurrence of the meeting, and shall arrange for alternative means of material distribution. Whenever possible, the IEC Administrators shall distribute the materials electronically.
- 4.1.8 The IEC Administrators shall notify all IEC members of any changes in meeting time, date or agenda as soon as discovered.
- 4.1.9 The IEC Administrators shall keep an archive of all copies of meeting agenda and all other documents.

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4.2 Meeting Procedure

- 4.2.1 Chair, Vice or nominated chair shall call meeting to order only when a quorum is formed.
- 4.2.2 Quorum should always be greater than half the total number of IEC members. Thus quorum should be half of the total number of members (N) plus one ($N/2 + 1$).
- 4.2.3 A quorum shall comprise members with the relevant expertise to effectively review business of the day. Presence of a community representative is critical in this regard.
- 4.2.4 A quorum, a majority of IEC membership must be present; including at least one member whose primary concerns is non-scientific.
- 4.2.5 If protocol(s) under review involves a target group of women, there must be a female member present to form a quorum.
- 4.2.6 If a quorum is not formed, the meeting will be rescheduled.
- 4.2.7 The Chair, Vice or acting chair shall follow the agenda for the progress of the meeting.
 - 4.2.7.1 The general framework of the agenda should be as follows:
 - 4.2.7.1.1 Opening of meeting by chairperson
 - 4.2.7.1.2 Apologies
 - 4.2.7.1.3 Adoption of the agenda, with or without changes
 - 4.2.7.1.4 Review & acceptance of previous meeting minutes
 - 4.2.7.1.5 Matters arising from previous meeting
 - 4.2.7.1.6 Declaration of conflict of interest
 - 4.2.7.1.7 New business
 - 4.2.7.1.8 Any other business
 - 4.2.7.1.9 Closure of the meeting by the chairperson

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- 4.2.8 If the meeting is to review a new submitted protocol, the principal investigator or co-investigator/team member of that protocol may be invited to brief the Committee on the purpose(s) of the study.
- 4.2.9 At the end of meeting(s), the IEC Administrators shall retrieve and destroy all documents (protocols, consent forms and other documents related to a particular project/study) which have been discussed and completed by the IEC.

4.3 Meeting Minutes

- 4.3.1 Meetings, all deliberations shall be recorded in writing or electronically.
- 4.3.2 Minutes shall include a list of attendees, actions taken by the IEC, the vote on those actions, including the number of members voting for, against and abstaining,
- 4.3.3 The basis for requiring changes in or disapproving research, and a written summary of the discussion of issues and their resolution.
- 4.3.4 The IEC Administrators shall also include a summary of each considered protocol in the minutes.
- 4.3.5 The IEC Administrators shall send a draft copy of the minutes to all IEC members either electronically or by fax or mail. The Administrators will send the draft with the copy of the next meeting's agenda not later than a week before the next meeting.
- 4.3.6 All IEC members shall review the minutes for accuracy and completeness. They may make recommendations to the minutes by communicating with the IEC Administrators, or at the next IEC meeting.
- 4.3.7 The Chair, Vice-Chair or acting chair shall review the minutes for accuracy and completeness and will sign the minutes together with the administrator.
- 4.3.8 The IEC Administrators shall archive the official minutes with the meeting's agenda and all relevant attachments.

5.0 SOP # 05: NEW PROTOCOL REVIEW

5.1 *New Protocol Submission*

5.1.1 Principal Investigators are responsible for following protocol submission procedures as outlined in this SOP.

5.1.2 Administrators are responsible for receipt and processing new protocol submissions.

5.1.3 Investigators shall submit a research protocol with the following required documents:

5.1.3.1 Scientific Review Committee approval letter from KHRC or Covering letter from the Head (Director)/ authorized representative of KHRC.

5.1.3.2 Summary of the protocol

5.1.3.3 A full protocol pre-reviewed by a scientific committee with approval letter. Protocol should include a statement on the involvement of policy makers (local, international) as part of the research team if applicable.

5.1.3.4 Enrolment forms

5.1.3.5 Questionnaires

5.1.3.6 Consent/Assent forms

5.1.3.7 Curriculum Vitas of investigators

5.1.3.8 Budget

5.1.3.9 Material Transfer Agreement if applicable

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- 5.1.4 The applicant must be the Principal Investigator (PI) or co-PI of the proposed research project
- 5.1.5 Protocol Application Form should be completed, signed, and dated by the PI/co-PI or his/her designee
- 5.1.6 Signed cover letter from the PI or co-PI and the head of the Institution (which should include physical address, fax number, telephone number, mobile number and email address) must be submitted
- 5.1.7 The applicant should submit hard copies of the full research protocol (number of copies to be determined by the IEC) and electronic version.
- 5.1.8 Applicants have the option of submitting electronically but will bear costs of printing and photocopying
- 5.1.9 All materials to be used in 'advertising' the research project, campaign materials, brochures etc should be submitted for ethical review
- 5.1.10 Up-to-date CVs of PI and or co-PI (CVs should be dated and signed). Bio-sketches of Co-Investigators should be submitted although full CVs may be demanded by the IEC.
- 5.1.11 Application fees (Institutional charge)
- 5.1.12 If the proposal is for an intervention study:
 - 5.1.12.1 For clinical trials Insurance certificate covering damages on participants and errors in the protocol implementation should be submitted.
 - 5.1.12.2 A letter showing commitment to make the products readily available to the study community should be submitted to the IEC

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5.1.13 Material Transfer Agreement (MTA) if applicable

5.1.14 Data Sharing Agreement (DSA) if applicable

5.1.15 ***Contents of full protocol***

- 5.1.15.1 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, plans for analysis and publication, personnel, budget & justification and timeframe of the project, dissemination plan and community sensitization if applicable.
- 5.1.15.2 The informed consent form and information leaflet, in both English and when necessary the translation into the local language and back translation into English. Back translation into English may be requested by the IEC.
- 5.1.15.3 Data collection tools such as questionnaires, interviews /discussion guides, checklists and case record forms must also be submitted
- 5.1.15.4 All materials to be used (including advertisements) for the recruitment of actual research participants must be attached to the protocol
- 5.1.15.5 If the proposed study is a clinical trial, the investigator's brochure which provides adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience of the study product to date (e.g. recent investigator's brochure, published data, summary of the product's characteristics etc), must be submitted

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- 5.1.16 Investigators must submit hard copies (number of copies to be determined by the IEC) of the full protocol and other documents at least two months prior to the commencement of the research study or four (4) weeks to the next scheduled meeting (usually 3rd Tuesday of each month)
- 5.1.17 The IEC Chair is responsible for determining whether a submitted protocol qualifies for expedited review.
- 5.1.18 Depending on the decision of the Chair on a particular protocol, primary reviewers would be appointed to review the protocol.

5.2 *Investigator(s) in IEC meetings*

- 5.2.1 Administrator(s) shall notify Principal Investigators of meetings scheduled to consider their submissions at least a week before the meeting date.
- 5.2.2 Administrator(s) shall notify the co-Investigator(s) about meetings in the absence of PI. An Investigator may be invited into the meeting room during consideration of his or her protocol.
- 5.2.3 Investigator(s) shall be invited to make a 10-15minute presentation. After the presentation, the Investigator(s) shall remain in the meeting to answer any questions, concerns and suggestions from members.
- 5.2.4 Investigators and any other attendees with a potential conflict of interest with the protocol shall be excused during voting period.
- 5.2.5 A Member shall vote for or against a protocol or abstain. An absentee member is allowed to send in his/her comments but cannot vote.
- 5.2.6 In order for a protocol to be approved, it shall receive the approval of two third (2/3) of voting members present at the meeting. The IEC may also decide to postpone decisions on a protocol if more information or consideration is required.

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- 5.2.7 If the IEC decides to disapprove a research proposal, the IEC shall put in writing reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- 5.2.8 After the committee has voted on a protocol, the committee shall notify the Investigator of its decision verbally or in writing.

5.3 *Expedited review (Meeting)*

- 5.3.1 Expedited review is when the process of review is speeded up so that an application does not wait for the normal scheduled full committee meetings
- 5.3.2 Expedited review should be requested and justified by the investigator through a written application to the IEC
- 5.3.3 For an application to qualify for expedited review, the proposed research should have minimal potential risks.
- 5.3.4 Minimal potential risks refers to risks which are not likely to cause serious or long lasting physical, psychological or socioeconomic harm.
- 5.3.5 Special attention should be given to research projects involving vulnerable populations (the issue of vulnerability to be emphasized under initial review procedures)
- 5.3.6 Research projects involving invasive procedures should not qualify for expedited review.
- 5.3.7 Research projects investigating sensitive social issues should not qualify for expedited review (Homosexuality, Commercial Sex Workers, drug abuse, child abuse, gender violence, Female Genital Mutilation, etc)
- 5.3.8 Research projects investigating issues that may potentially have serious negative impact at community, ethnic group or population level should not qualify for expedited review
- 5.3.9 Amendments from research projects with minimal potential risk to participants and community may qualify for expedited review

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- 5.3.10 Upon receiving an application for expedited review, the IEC Administrator in consultation with the Chairperson/Vice makes the initial assessment to determine if it qualifies for expedited review
- 5.3.11 If it qualifies for expedited review, IEC member(s) whose area of expertise and experience is in the same field as the proposed research project and are available should be assigned to review the proposal. If the review involves a project amendment, the selected members to review the project should preferably be members who reviewed the previous version of the protocol.
- 5.3.12 A summary of the protocols reviewed through the expedited process should be submitted to members of the full IEC, before a full board meeting.
- 5.3.13 A decision arising from an expedited review will be provisional pending confirmation from the full board meeting. Such decision should be communicated to the investigator in writing. In case of a provisional approval, the investigator may proceed with the study.
- 5.3.14 Expedited review shall not take longer than 2 weeks to review.
- 5.3.15 The expedited review comments and approval or disapproval of the application should be tabled as part of the agenda for the next full IEC meeting.
- 5.3.16 In the event that a protocol did not attain approval from an expedited review, the protocol should be submitted for a full IEC review.
- 5.3.17 The full IEC meeting has the power to confirm, modify or reverse a decision emanating from the expedited review. If the decision of the full IEC committee is contrary to the decision emanating from the expedited review, detailed reasons and explanations should be recorded in minutes.
- 5.3.18 The applicant has to be informed about any modifications that the full IEC committee may have recommended and the ethical justification for such a decision

5.4 Continuing/Regular review (Meeting)

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- 5.4.1 The Chair and IEC members are responsible for determining whether a research is reviewed annually, or more frequently appropriate to the degree of risk.
- 5.4.2 The IEC is also responsible for determining whether an independent data and safety monitoring board is required.
- 5.4.3 The Principal investigator of the research is responsible for keeping the IEC informed of significant findings that affect the risk/benefit ratio and thus the need for more frequent review.

5.4.4 *Frequency of continuing review*

5.4.4.1 At a research activity's initial review, the IEC shall determine:

5.4.4.1.1 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 or at least once before the end of the research.

5.4.4.1.2 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.

5.4.5 The investigator will utilize the continuing review form to complete the annual review report. The report will include all required elements, including the following:

- 5.4.5.1 Number and demographics of participants enrolled
- 5.4.5.2 Changes in principal and/or associate investigator(s)
- 5.4.5.3 A summary description of subject experiences
- 5.4.5.4 Serious Adverse Events (SAEs) experienced
- 5.4.5.5 Reasons for withdrawals from the research by participants (where available)
- 5.4.5.6 Research results obtained thus far

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5.4.5.7 Current risk-benefit assessment based on study results

5.4.5.8 Any new information since the IEC's last review.

5.4.6 If the investigator cannot provide any of the required information, s/he will provide justification for the delay in the report, and a timetable for provision of the information.

5.4.7 Investigator(s) shall submit a copy of the consent documents and procedures currently in use.

5.4.8 Investigator(s) shall submit one hard copy of the continuing review report, with original signature. Investigator(s) are encouraged to submit an electronic copy of the review report via e-mail or disc.

5.4.9 Upon receipt of the continuing review report, Administrator(s) shall conduct a pre-committee review to ensure all required elements are present.

5.4.10 Administrators will place the continuing review report on the next IEC meeting's agenda.

5.4.11 IEC members will consider and vote upon all continuing review reports in full meeting utilizing the protocol voting procedure. The risk/benefit ratio may change over time. Criteria to approve or disapprove continuation of research are the same as criteria for approval of an initial research project.

5.4.12 The IEC will 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(s) have current IEC approval.

5.4.13 After reassessment, the IEC may require that the research be modified or halted.

5.4.14 The IEC may also impose special precautions or relax special requirements it had previously imposed on the research protocol.

5.4.15 Administrator(s) shall archive continuing review reports and supporting materials with the relevant meeting minutes.

5.4.16 ***Timing of Continuing Review***

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5.4.16.1 If the IEC has not reviewed and approved a research study by the end of the IEC's study's expiration date, IEC approval has expired and the research should stop.

5.4.16.2 However, if the investigator is actively pursuing renewal with the IEC and the IEC believes that an over-riding safety concern or ethical issue is not involved, the IEC may permit the study to continue for the brief time required to complete the review process.

5.5 Amendment(s) review (Meeting)

5.5.1 Amendments to protocols shall not be implemented until reviewed and approved by the IEC.

5.5.2 The secretariat shall manage protocol amendments.

5.5.3 Amendments shall be submitted to the committee for either "expedited" review or 'regular' review.

5.5.4 PI(s) shall submit amendment(s) package to secretariat with completed amendment protocol and related documents.

5.5.5 An amendment memorandum or cover letter shall state/describe;

5.5.5.1 Amendment(s) made,

5.5.5.2 Reason(s) for amendment(s),

5.5.5.3 Any untoward effects from original protocol

5.5.5.4 Expected untoward effects because of amendment(s).

5.5.6 Administrator(s) shall follow guidelines in SOP# 05 for amendment(s) received

5.5.7 Administrator(s) shall verify amendment(s) and related document(s) with original protocol.

5.5.8 Administrator(s) shall then:

5.5.8.1 Inform the Chairperson verbally or in writing.

5.5.8.2 Send amendment memorandum or cover letter, amended protocol and related documents to Chairperson within two working days of receipt of amendment.

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- 5.5.9 Chairperson shall determine type of review for amendment(s)
- 5.5.10 Amendment(s) with increased risk to study participants shall not qualify for expedited review.
- 5.5.11 Amendment(s) that have one or more of the following features shall not qualify for expedited review;
 - 5.5.11.1 Change in study design
 - 5.5.11.2 Additional treatments or the deletion of treatments
 - 5.5.11.3 Any changes in inclusion/exclusion criteria
 - 5.5.11.4 Change in method of dosage formulations (e.g. oral changes to intravenous)
 - 5.5.11.5 Significant decrease or increase in dosage amount.
 - 5.5.11.6 Significant change in number of participants (for example there would be a significant increase if there are <20 participants enrolled, a change of 5% is significant; if there are >20 participants enrolled, a change of 20% is significant.
 - 5.5.11.7 significant decrease in participants enrolled alters the fundamental characteristics of the study
- 5.5.12 If the Chairperson decides the protocol requires full committee approval, s/he shall indicate this decision on the checklist, sign and date the form
- 5.5.13 If an amendment is received just prior to the committee meeting, the chairperson may decide to review the amendment in full committee, even though the amendment may be expedited.
- 5.5.14 Upon receipt of chairperson decision, Administrator(s) shall:
 - 5.5.14.1 Place the protocol amendment request on the agenda for the next convened meeting
 - 5.5.14.2 Distribute to each committee member amended document(s)
- 5.5.15 Chairperson shall call for a vote on proposed amendments
- 5.5.16 Administrator(s) shall note recommendations or changes to amendments and forward to PI(s)

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5.5.17 If the committee does not approve the protocol amendment, the notification to the investigator shall also state the reason for not approving the amendment.

5.5.18 Administrator(s) shall place the original completed documents, the “clean” version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

5.6 *Ad hoc /extraordinary reviews or meetings*

5.6.1 Ad hoc/Extraordinary IEC meeting shall be held if urgent issue(s) that do not qualify for expedited review but require a full IEC meeting are encountered.

5.6.2 Administrator(s) shall circulate notice giving the date, venue, time and agenda of ad hoc/extraordinary meeting at least 48 hours before the day of the meeting

5.6.3 The general framework / agenda shall be as follows:

5.6.3.1 Opening of ad hoc meeting by the chairperson

5.6.3.2 Apologies

5.6.3.3 Adoption of the agenda

5.6.3.4 Reasons for which ad hoc meeting was convened

5.6.3.5 A quorum should be present before ad hoc meeting can proceed

5.6.3.6 Closure of the ad hoc meeting by the chairperson

5.6.3.7 Minutes of the ad hoc meeting should be tabled in the next scheduled IEC meeting for confirmation and signing

5.7 *Decisions of committee and procedure*

5.7.1 IEC can only make decisions if the quorum requirements as stipulated in the relevant SOP are satisfied.

5.7.2 Any member with conflict of interest regarding a particular proposal must not take part in the review of the proposal and subsequent

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decision making process. Member with conflict of interest must excuse himself/herself

- 5.7.3 Non-members such as project PIs and independent experts may be consulted as part of the review process
- 5.7.4 A decision should only be taken after there has been sufficient time to allow for review and discussion of an application in the absence of non-members from the meeting.
- 5.7.5 Only IEC members who participated in the review process and deliberations should take part in the decision-making process.
- 5.7.6 IEC decisions shall be either unanimous when all members are in agreement or by consensus when there is voting or the position voted for by the majority becomes the IEC decision.
- 5.7.7 In case there is a tie, other members who were absent should be consulted otherwise independent expert opinion should be sought.
- 5.7.8 IEC decisions regarding applications shall be:
 - 5.7.8.1 Full Ethical Approval (FEA)
 - 5.7.8.2 Conditional Ethical Approval (CEA) for proposal with minor changes required which can be verified by secretariat without submitting to full IEC meeting
 - 5.7.8.3 Major changes necessitating resubmission of the application to full IEC meeting or to appointed members of the IEC
 - 5.7.8.4 Deferment, pending a decision at a later date.
 - 5.7.8.5 Disapproval
 - 5.7.8.6 For any decision made by the IEC, clear reasons and justifications should be given and should be documented in the minutes and in the communication to the applicant

5.8 *Communicating decisions to Investigators*

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- 5.8.1 Decisions regarding submitted protocols should be officially communicated, in writing, to the applicant within ten (10) working days after the meeting that made the decision(s).
- 5.8.2 Communication of the IEC decision shall include but not limited to the following:
 - 5.8.2.1 The name, title and address of the applicant
 - 5.8.2.2 The exact title of the proposal reviewed
 - 5.8.2.3 The name of the site(s) or study area
 - 5.8.2.4 The names and identification numbers (versions numbers/dates) of the reviewed documents.
 - 5.8.2.5 A clear statement of the decision reached by the IEC
 - 5.8.2.6 The name of IEC taking the decision: a letter head of the IEC suffices.
 - 5.8.2.7 The date of the decision and signature of the Chairperson/Vice Chairperson or any voting member assigned to do so by the Chairperson.
 - 5.8.2.8 In case of a conditional decision, any requirements by IEC, including suggestion for revisions should be clearly explained in writing to the applicant.
 - 5.8.2.9 In case of a positive decision, a statement of responsibilities of the applicant and any requirements as stipulated in the decision by the IEC
 - 5.8.2.10 The validity period of the approval
 - 5.8.2.11 The final approval certificate/letter shall be signed by chairperson or vice chairperson in the absence of the Chair.

5.9 *Approval(s) and renewal period(s) or durations*

5.9.1 *Conditional Ethical Approval (CEA)*

5.9.1.1 Conditional Ethical Approval (CEA) shall expire when conditions stipulated are addressed and received by secretariat

5.9.1.2 Conditional Ethical Approval (CEA) shall have a maximum duration of three months post CEA decision for PIs to address concerns of committee.

5.9.2 *Full Ethical Approval (FEA)*

5.9.2.1 FEA for six-month cycle studies that require between one month – six months period for research

5.9.2.1.1 Renewal window is one month prior to expiration date

5.9.2.1.2 Renewal shall require progress report and or justification

5.9.2.2 One year of twelve-month cycle studies that require between a year – several years period for research

5.9.2.2.1 Renewal period is yearly (plus progress report)

5.9.2.2.2 Renewal window is one month prior to yearly renewal date

5.10 *Use of Data and Safety Monitoring Board (DSMB)*

- 5.10.1 In larger studies or trials, the IEC may also require a DSMB be formed to keep the IEC up-to-date of the balance between risks and benefits.
- 5.10.2 The primary responsibility of a DSMB is to safeguard human participants by analyzing accumulating data relevant to the risks and benefits on a regular basis.
- 5.10.3 In long-term trials, the DSMB reviews data periodically to assess effectiveness and toxicity, and to decide if and when the data are sufficiently favourable to one treatment that the study should be discontinued.
- 5.10.4 The DSMB also decide whether adverse effects are serious enough to warrant termination of the study.

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**6.0 SOP # 06: REVIEW OF SAFETY/SERIOUS ADVERSE EVENTS (SAEs)
REPORTS**

6.1 This SOP provides instructions on the review and follow-up on reports of adverse experience(s) and unexpected events for any active study approved by the committee.

6.2 This SOP applies to the review of SAE and unexpected events reports submitted by investigators, DSMB, Local safety monitor, IRB and any other intended parties

6.3 Administrators shall review SAEs to determine whether the report requires full committee review in consultation with Chairperson or other qualified committee member(s).

6.4 Criteria of the review shall be as follows:

6.4.1.1 If assessment of adverse experience is unknown or unlikely, the report shall be forwarded for a full committee review.

6.4.1.2 If assessment of adverse experience is possibly caused by, or probably caused by the investigational drug, a full committee meeting shall review the SAE.

6.4.1.3 If an adverse experience/investigational new drugs safety report has previously been seen by full committee and resubmitted by another investigator in the same study (as part of a multi- Centre study), this notification shall not require full committee review instead be reviewed by the Chairperson or other qualified committee members.

6.5 After reviewing SAE report(s), the Chairperson or designee shall call for full committee discussion on the study and similar adverse experiences or advisories.

6.6 The Chairperson or another committee member may call for a consensus on whether to:

6.6.1.1 Request an amendment to the protocol or consent

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6.6.1.2 Request further information on SAE

6.6.1.3 Suspend or terminate the study due to SAEs on participants

6.7 If any of the above actions are taken, the secretariat shall notify the investigator of the action taken.

6.8 If the committee takes no action, it shall be noted in the minutes and a formal letter to the investigator notifying him/her of the committee's decision.

6.9 The letter shall be signed by Chairperson or vice Chairperson in the absence of the Chair and date of delivery shall be recorded.

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7.0 SOP # 07: REVIEW OF FINAL REPORTS

- 7.1 The purpose of this SOP is to provide instructions on the review and follow-up of final reports for any study previously approved by the IEC.
- 7.2 Final report(s) shall be submitted to the committee after the last participant had completed all visits and all adverse experiences have been brought to appropriate resolution.
- 7.3 Although the IEC could provide a final report format to the investigator, any mechanism or format may be used, provided that the information submitted is sufficient.
- 7.4 It is the responsibility of the secretariat to review the report for completeness before making copies for the committee meeting.
- 7.5 Administrator(s) shall be guided by SOP# 05 for receiving and checking final report package(s).
- 7.6 Administrator(s) shall read submitted report and give a briefing to the Chairperson before making copies and distributing to all committee members.
- 7.7 Each committee member shall review a copy of the final report before deliberations.
- 7.8 Request for further information to take action may be requested from PI(s) before concluding on the research findings.
- 7.9 Administrator(s) shall note the decision in the meeting minutes.
- 7.10 Administrator(s) shall notify investigator(s) of the decision taken.
- 7.11 Final report shall be filed and consider the study endorsed as closed.

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8.0 SOP # 08: NON – COMPLIANCE/VIOLATIONS INTERVENTION

8.1 The purpose of this SOP is to provide instructions for identifying violations/non-compliance and actions thereafter by the IEC.

8.2 The secretariat is responsible for collecting and recording violations/non-compliance of research activities.

8.3 Violations/non-compliance occurs when:

8.3.1.1 Researcher(s) fail to comply with IEC conditions/guidelines

8.3.1.2 Researcher(s) fail to respond to request by the IEC.

8.3.1.3 Researcher(s) fail to comply with regulatory requirements.

8.4 *Research Misconduct includes but is not limited to:*

8.4.1 Conducting health research which involves human participants or potentially affects humans in the area it was conducted without first obtaining ethical approval.

8.4.2 Collecting samples or information from human participants without first obtaining valid informed consent

8.4.3 Sharing samples collected from human participants with other researchers or institutions without ethical approval to do so and without a signed Material Transfer Agreement.

8.4.4 Sharing samples collected prospectively from human participants with other researchers or institutions without the informed consent of the sample donors to do so. The IEC may waive the requirement for informed consent in the case of archived samples if the justifications are considered to be ethically and scientifically sound by the IEC.

8.4.5 Failure to submit mandatory reports such as SAE reports, progress reports and final reports to the IEC

8.4.6 Failure to uphold privacy and confidentiality of participants' information

8.4.7 Failure to report deviations from the approved protocol.

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- 8.4.8 Fabricating, falsifying, or knowingly plagiarizing data
- 8.4.9 Misuse of project funds at the expense of the approved project activities
- 8.4.10 Unjustifiable deviations.
- 8.4.11 Forgery of IEC documents – (alteration of approval letter/certificate; Material Transfer Agreement, etc)

- 8.5 Whenever non-compliance has been observed, it shall be ensured that the investigator information is placed on the agenda of an immediate committee meeting.
- 8.6 A file shall be maintained that identifies investigators found to be in non-compliance with regulations or who fail to respond to the committee's requests or conditions.
- 8.7 The committee shall terminate approval of current studies or refuse subsequent applications from investigator(s) cited.
- 8.8 The committee shall notify the investigator(s) of the committee's action in writing.
- 8.9 Copies of the termination letter shall be sent to relevant regulatory authorities and sponsor(s) and inform management of the institution.
- 8.10 The Committee's action shall be followed up after a ten (10) working days or reasonable time decided by the committee.

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9.0 SOP # 09: MANAGEMENT OF PROTOCOL TERMINATION

9.1 This procedure describes how protocol termination is managed by the KHRCIEC and applies to protocols approved by KHRCIEC.

9.2 Protocols/research shall be terminated by the IEC per:

- 9.2.1.1 recommendation from management of KHRC
- 9.2.1.2 recommendation from DSMBs
- 9.2.1.3 recommendation from FDB
- 9.2.1.4 IEC violations (ethical breaches/research misconduct)
- 9.2.1.5 any other authorized regulatory body

9.3 It is the responsibility of the Chairperson to terminate research in the interest of study participants' health or welfare.

9.4 The secretariat is responsible for management of the termination process(es).

9.5 *Termination procedure/instruction*

9.5.1 Upon receipt of recommendation for protocol termination the secretariat shall verify justification by doing the following within one working day of receipt:

- 9.5.1.1 Contact sponsor(s) for comments on termination based on received violations.
- 9.5.1.2 Interview violating PI(s) based on reasons and accrued data.
- 9.5.1.3 Review study file of research for any IEC violations by PI(s)

9.5.2 Administrator(s) shall notify Chairperson regarding request(s) for protocol termination by sending a copy of termination justification report to Chairperson within two working days upon receipt of termination request(s).

9.5.3 Chairperson shall review justification, reason(s) and accrued data and call an emergency (ad hoc) meeting.

9.5.4 Administrator(s) shall do the following after termination is endorsed:

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- 9.5.4.1 Send termination letter to PI(s) and sponsor(s) with justification.
- 9.5.4.2 Keep original version of termination memorandum and related documents as per SOP # 14.
- 9.5.4.3 Place protocol and related documents into the inactive protocol folder

10.0 SOP # 10: OVERSIGHT/MONITORING VISITS

10.1 Purpose

10.1.1 This SOP provides a guide for the committee to exercise oversight responsibilities for studies it has reviewed. This SOP applies to any visits and/or monitoring of studies approved by the IEC.

10.1.1.1 It is the responsibility of the IEC to perform or designate qualified agent(s) to perform this activity on its behalf.

10.1.1.2 The secretariat in consultation with the chairperson shall initiate an on- site evaluation of a study for cause or for a routine audit.

10.2 Announced oversight/monitoring visit

10.2.1 Announced monitoring visit(s) shall be conducted on all reviewed research

10.2.1.1 Administrator(s) shall notify investigator(s) in writing at least one week prior to oversight visit(s).

10.2.1.2 Administrator(s) on behalf of the visiting team shall make appropriate travel arrangements for oversight visit(s).

10.2.1.3 Oversight/monitoring team shall review the committee files for the study and make appropriate notes, or copy some parts of files for comparison with files on the field or in use.

10.3 Unannounced oversight/monitoring visit

10.3.1 An unannounced monitoring visit(s) shall be conducted at random to research based on the following criteria:

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- 10.3.1.1 Research that fails to submit progress reports as per regulations after two reminders.
- 10.3.1.2 Research with prolong completion beyond approved time frame (without renewal).
- 10.3.1.3 Research suspected to have changed objectives as approved by the committee.

10.4 *Types of oversight/monitoring*

10.4.1 Passive monitoring: The IEC receives information about research projects that it reviews and uses the information to assess if projects are progressing well devoid of scientific and ethical breaches

10.4.1.1 *Serious Adverse Events reports*

10.4.1.1.1 Investigators and sponsors are obliged to report in writing any serious adverse events (SAEs) to the IEC within 48 hours.

10.4.1.1.2 IEC SAE report template may be used.

10.4.1.1.3 AEs should be recorded by the investigators and reported to the IEC as and when progress reports are due.

10.4.1.2 *Progress reports*

10.4.1.2.1 PIs shall submit progress reports at intervals stipulated by the IEC

10.4.1.2.2 PIs shall submit Material Transfer Agreements to the IEC which states quantities, types and specific purpose of any samples to be moved from the institution where they are collected to another recipient institution.

10.4.1.2.3 PIs shall submit DSMBs reports if requested

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10.4.1.2.4 Investigator(s) shall be obliged to submit copies of publications emanating from approved protocols to the IEC.

10.4.2 **Active monitoring:** IEC members physically visit research project(s) in the field to assess if projects are being conducted as per approved protocols. The ideal is that each and every approved study should be actively monitored to ensure adherence of health research ethics.

10.4.2.1 In the event that there is a study being implemented without ethical approval, urgent site visit should be carried out and appropriate action taken.

10.4.2.2 IEC members should use the IEC monitoring guide in order to ensure that pertinent issues are assessed during the visit.

10.4.2.3 Number of IEC members to undertake an oversight visit should depend on workload of inspection activities to be performed.

10.4.2.4 To maximize objectivity in oversight visit(s), at least 2 members with relevant/diverse expertise shall make up an oversight team.

10.4.2.5 An oversight team may preferably include a community representative from the IEC where possible.

10.5 *Reasons for additional oversight visits*

10.5.1.1 IEC oversight visits in response to reports made directly to the IEC or circulating in the community

10.5.1.2 Increased frequency of serious adverse events reports

10.5.1.3 Failure to submit progress reports or final report

10.5.1.4 Reports of suspected research misconduct

10.5.1.5 Researchers who extend their research beyond the approved time frame without formal notification and approval by the IEC

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10.5.1.6 Researchers that are suspected to have changed their objectives and design of the study without prior approval

10.5.1.7 Any other reason that the committee feels warrants further follow-up

10.6 *During oversight/monitoring visit(s)*

10.6.1 The visiting team shall:

10.6.1.1 Review informed consent document(s) to make sure that the investigator(s) is using the most recent approved version.

10.6.1.2 Randomly review 10 – 25% of participant files to ensure that participants are signing/thumb printing correct consent form.

10.6.1.3 Observe the informed consent process (if possible)

10.6.1.4 Review relevant study files to ensure documentation is filed appropriately and confidentiality.

10.7 *After oversight/monitoring visit(s)*

10.7.1 The committee representative(s) that made the visit shall:

10.7.1.1 Debrief investigator(s) before departure.

10.7.1.2 Write a report using the checklist for monitoring visits (form # 09) two weeks post visit describing findings during the audit.

10.7.1.3 Submit copy of report to secretariat files for full committee review

10.7.1.4 Send a final report (via secretariat) to investigator(s).

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11.0 SOP # 11: COMMUNICATION WITH STAKEHOLDERS

11.1 The purpose of this SOP is to ensure proper completion, distribution and filing of verbal and written communication and other study-related or process-related information with investigators, sponsors, participants, institutes, DSMBs, ethics committees and any other relevant agencies. This SOP applies to all communicating activities of the KHRCIEC.

11.2 Procedure(s) or instruction(s)

11.2.1 The committee shall utilize different communication mechanisms; that may be handwritten, typed or computer-generated.

11.2.2 Communication records of/to the committee shall contain, but not limited to the following:

11.2.2.1 date of communication,

11.2.2.2 study information (e.g. sponsor, protocol number, investigator),

11.2.2.3 name of person contacted, contact address, telephone number, and e-mail,

11.2.2.4 summary of communication made, notation of any follow-up necessary and signature of individual(s) making the record.

11.2.3 Copies of communication(s) shall appropriately be filed.

11.2.4 Records must be kept in a manner that confidentiality is maintained

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12.0 SOP # 12: ENGAGEMENT OF CONSULTANT(S)/EXPERTS

12.1 The purpose of this SOP is to provide procedures for engaging the expertise of a professional as a consultant to the committee. If a proposal requires expertise that the IEC does not have, Administrator(s) in consultation with Chairperson may engage independent experts to review and give their views.

12.1.1 The Secretariat shall keep an up-dated list of experts with their CVs, which shall be reviewed annually by the Committee.

12.1.2 Independent experts shall sign privacy and confidentiality forms as well as Conflict of Interest forms to ensure that the information in the proposal is protected and that the consultants do not have any conflict of interest regarding proposals reviewed.

12.1.3 The IEC may ask specific questions that could guide the review by the experts.

12.1.4 Experts shall only give their views and respond to specific asked, but do not decide status application(s) or protocol(s).

12.1.5 Expert(s) may be invited to an IEC meeting to respond to questions

12.1.6 Experts shall not participate in the decision-making process.

12.1.7 The committee may further be supported in its reflections on specific protocols or requests for advice on specific ethical issues from independent advisors.

12.1.8 Administrators shall retrieve all IEC documents with consultants after each review assignment

12.2 Selection of Independent consultants

12.2.1 The secretariat shall create a list of consultants/experts.

12.2.2 The creation of list/roster of experts shall involve conducting a qualification review of prospective consultants and making decision based on expertise, availability and independence criteria.

12.2.3 It shall be the responsibility of the secretariat to nominate the name of a consultant.

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12.2.4 Consultants shall provide the secretariat their Curriculum Vitae

12.2.5 Consultants shall sign a Confidentiality/Conflict of Interest Agreement

12.2.6 If the committee determines that a study shall involve procedures not within the area of expertise of the committee members or consultants, the committee may invite individuals with competence in special areas to assist in the review

12.3 Termination of consultant Services

12.3.1 Consultation services may be terminated by either consultants themselves or the committee.

12.3.1.1 Upon termination of the consultant's services, the secretariat shall ensure that all documentation and the reasons for discontinuation of the services are filed with administrative documents.

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13.0 SOP # 13: RESPONSES TO PARTICIPANTS REQUESTS

13.1 This SOP applies to all requests concerning the rights and well-being of the participants in studies reviewed and approved by the IEC. It provides guidelines for dealing with and accommodating requests by participants regarding their rights as participants in any approved research study.

13.2 It is the responsibility of all Staff and committee members acting on behalf of the committee to facilitate participants' requests.

13.3 Informed Consent documents reviewed by the committee may routinely contain the statement, "Questions regarding the rights of a subject/patient" may be addressed to the Chair through the Administrator, address and phone number of Administrator inserted in consent form.

13.4 The IEC shall designate the Administrator as the person responsible for communicating with participants regarding their rights as study participants. Delegation of this responsibility to another member is acceptable as long as delegation is documented in writing. Delegation to non-committee members is not permitted.

13.5 Handling a request

13.5.1 Upon receiving an inquiry from a study participant, the KHRCIEC Staff shall do the following:

13.5.1.1 Report the request to secretariat of IEC

13.5.1.2 Provide assistance in contacting the Chairperson, but shall not provide comments/opinions about the inquiry.

13.5.2 Administrator(s) shall:

13.5.2.1 Communicate with participant on his/her rights based on consent/information sheet

13.5.2.2 Refer inquiry to the Chairperson

13.5.3 The Chairperson shall document the communication for the committee study file, request follow-up information, provide advice as required, inform the other committee members of the inquiry,

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and follow-up at the next meeting and delegate these tasks to secretariat who shall then do the following:

- 13.5.3.1 Record information and any actions or follow-ups taken.
- 13.5.3.2 Report to the committee about the action taken and the outcomes.

14.0 SOP # 14: ARCHIVING IEC DOCUMENTS

14.1.1 This SOP outlines the process for archiving documents of the committee to maintain confidentiality and privacy of researchers and participants.

14.2 Archiving of ongoing/current study protocols

14.2.1 Administrator(s) shall archive electronic copy and paper original copies of protocols and related study documents till study completion.

14.3 Archiving of completed study protocols

14.3.1 The IEC Secretariat shall archive electronic copies of research protocols 15 years post research completion/closure.

14.3.2 Paper original copies shall be archived 10 years post research completion/closure.

15.0 SOP # 15: SOPs revision(s)

- 15.1 This SOP provides guideline for the revision/review of SOPs of the committee to reflect current procedures of the committee.
- 15.1.1 SOPs shall be reviewed annually (last meeting of committee in each calendar year).
- 15.1.2 Any committee member could propose revision/update in an SOP before annual revision date.
- 15.1.3 Individual proposed revision shall be communicated during a full committee meeting with justification.
- 15.1.4 Administrator(s) with approval from the chair and or full committee, may request minor changes be made directly to SOP(s).
- 15.2 **Annual review**
- 15.2.1 SOPs shall be evaluated for accuracy, context and appropriateness in an annual review.
- 15.2.2 Administrator(s) shall alert the committee of an annual review requirement one month prior to review.
- 15.2.3 Administrator(s) could assign primary reviewers to ensure that the SOPs reflect the most current outline of procedures.
- 15.2.4 If SOPs do not need revision, the committee shall capture in annual meeting as such and adopt it effective for the preceding calendar year.

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16.0 GLOSSARY OF TERMS AND DEFINITIONS

16.1 In order to facilitate the use and understanding of the SOPs, this section standardizes definitions, terms, abbreviations, phrases, used by the Institutional Ethics committee of the Kintampo Health Research (KHRCIEC).

16.2 It is the responsibility of the secretariat, members of the committee and the chairperson to define or determine the appropriateness of the descriptions or definitions.

Terminology	Description/Definition
Administrative staff	Staff responsible for the day-to-day administrative functions and duties, which support the activities and responsibilities of IEC members.
Chairperson	A duly elected member of the committee presiding over meetings and acts in that capacity outlined in SOP # 03. He/she is responsible for expedited approvals on behalf of the committee.
Vice chairperson	A duly elected member of the committee that presides over a meeting in the absence of the chairperson. He/she is responsible for expedited approvals on behalf of the committee in the chairperson's absence.
Acting Chairperson	A voting member of the Committee who is nominated by the house to preside over a meeting in the absence of the chair and vice chair.
Committee members	Individuals serving as regular or alternate members on a duly constituted body/group in accordance with membership requirements set forth in SOP # 01. Individuals qualified to vote at a duly convened IEC meeting and non-voting members.
Ethics committee	A body whose responsibility is to ensure the protection of rights, safety and well being of human participants involved in bio-medical research and to provide public

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	assurance of that protection
Project manager	An individual responsible for coordinating an investigation/research study.
Site coordinator	The person at the study site who is responsible for managing a study. This person can also be referred to as a Project Manager.
Clients	Investigators, institutions sponsors or sponsor's representatives. Clients requesting services of the IEC are asked to accept and abide by the procedures set forth in this document (SOP).
Adverse Event (AE)	Any undesirable experience associated with the use of a medical product/device in a participant.
Serious Adverse Event (SAE)	<p>The Adverse Event (AE) is SERIOUS when the outcome is:</p> <p>Death - if death is suspected as being a direct outcome of the adverse event.</p> <p>Life- Threatening – If there is substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death. <i>Examples: Pacemaker failure; gastrointestinal haemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.</i></p> <p>Hospitalization (initial or prolonged) -If admission to the hospital or prolongation of a hospital stay results because of the adverse event. <i>Examples. Anaphylaxis pseudo membranous colitis or bleeding causing prolong hospitalisation.</i></p> <p>Disability -if adverse event resulted in a significant,</p>

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	<p>persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. <i>Examples: Cerebrovascular accident due to drug-induced hyper coagulability; toxicity, peripheral neuropathy.</i></p> <p>Congenital Anomaly -If there is suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. <i>Examples: Vaginal cancer in female off spring from diethylstilbestrol during pregnancy,' malformation in the offspring caused by thalidomide.</i></p> <p>Permanent Impairment or Damage - If any suspicion that the use of a medical product may result in a condition, which required medical or surgical intervention to preclude permanent impairment or damage to a participant. <i>Examples; Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage burns from radiation equipment requiring drug therapy, breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.</i></p>
Addendum	Additional or supplementary documents to a protocol
Amendment	A change to a study protocol during the planning or course of the research. The amendment is an unforeseen change to the study plan that requires formal approval by the sponsor and IEC before implementation.
Audit	A systematic and independent examination of research approved activities and documents to determine whether approved activities were/are conducted and data were/are recorded and accurately reported according to

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	SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements
Confidentiality	Prevention of disclosure, to other than authorized individuals, of committee information and documents
Conflict of Interest	<p>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 duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when:</p> <ul style="list-style-type: none"> (i) An individual's private interest differs from his or her professional obligations to the institute. (ii) Professional actions or decisions occur that an independent observer might reasonably question. (iii) A conflict depends upon situation and not on the character or actions of the individual. <p>Potential conflicts of interest must be disclosed and managed as per SOP # 02.</p>
Deviation	Any instance in which the current approved procedure/activity/SOP is not adhered to by persons (PIs) or clients of the IEC.
Expedited review	A review process by only a few designated committee members who then report the decision to the full committee meeting. An expedited review is a speedy review for minor changes to a protocol and for research that pose minimal risk to participants.
Expedited approval	A committee's approval granted only by the Chairperson of the committee or designated member for minor changes to current approved research activities and for research, which involves no more risk than 'minimal risk'.
Full Ethical Approval (FEA)	Approval of a reviewed protocol without ethical or scientific breaches that receives majority of votes during

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	review process as per a full committee review, expedited or ad hoc review meetings
Conditional Ethical Approval (CEA)	Approval of a reviewed protocol with some degree of ethical or scientific breaches that receives stipulated conditions during review process to be addressed by investigators as per a full committee review, expedited or ad hoc review meetings
Progress Report	An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the committee. Generally, these reports are due annually. More frequent reports may be requested at the discretion of the committee.
Final report	An obligatory review of study activities presented as a written report to the committee after a research or the last participant has completed all visits and all adverse experiences have been brought to appropriate resolution.
Inactive study files	Supporting and approved documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to participants, scientific evaluations) that correspond to each study approved by the KHRCIEC for which a final report has been reviewed and accepted.
Independent consultant	An expert who gives advice, comments and suggestion upon review of protocols with no affiliation to the institute(s) or investigators proposing the research protocols.
Inspection	The act by regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be

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	related to a clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organizations (CROs) facilities, office of ethics committees, or at other establishments deemed appropriate by the regulatory authorities.
Investigation/protocol files	A file keeping research Protocols that are under investigation or on-going study.
Investigational Medical Device	A medical device, which, is the object of clinical research to determine its safety or effectiveness.
Medical Device	A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intraocular lenses, and orthopaedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis of disease and other conditions.
Master file	A file for storage of the originally signed and dated documents.
Minutes	Official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) independent committee review meeting. The minutes identify each protocol and/or activity and record the outcomes of each voting action. The record notes the number for, number against, the number of abstaining votes, and the reason for the abstention(s), without identifying the individual members' names.
Monitoring visit	An action that the IEC visit study sites to assess how investigator(s) are conducting research, taking care of participants, recording data and reporting their observations, especially serious adverse events found

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	during the studies as per approved protocol.
New Study	A study protocol presented to the committee for approval for the first time and not previously approved by this committee. This includes re-application for those studies denied approval by the committee.
Non-compliance record	A list containing the identity of investigators who are considered by the committee to be non-compliant with ethical guidelines, FDB regulations or who fail to respond to the committee's requests and the incident justify the reason for the termination of the study.
Scientist	Professional with either bio-medical or non-biomedical background by training
Participants' rights	Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family. The foundation of freedom, justice and peace in the world. It is essential that Human Rights should be protected by the rule of law.
Quorum	Attendance at any convened meeting of the committee where majority (N/2+1) of the regular (or alternate) members, including at least one physician and one layperson, is maintained throughout the discussions and voting process of a meeting.
Non-significant Risk Device (NSR)	An investigational device that does not pose a significant risk.
Significant Risk Device (SR)	A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the participant, (2) is purported or represented to be for use in supporting or sustaining human life and presents potential for serious risk to the health, safety, or welfare of the participant, (3) is for use of substantial importance in diagnosing, curing, mitigating, or treating disease, or

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	otherwise preventing impingement of human health and presents a potential for serious risk to the health, safety, or welfare of the participant, or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participant.
Standard Operating Procedure (SOP)	Detailed, written instructions, in a format, describing activities and action undertaken by an organization or entity to achieve uniformity of the performance of a specific function.
Vulnerable participants	Vulnerable participants include; children, prisoners, pregnant women, handicapped or mentally challenged persons, and economically or educationally disadvantaged persons who are likely to be coerced or unduly influenced.

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REFERENCES

1. 45 Code of Federal Regulations 46.115 IEC Records, 108.b IRB Functions and Operations
2. The Belmont report
3. CIOMS guidelines
4. WHO guidelines for Biomedical Research
5. ICH-GCP Guidelines
6. Declaration of Helsinki

APPENDECES

Appendix 1: Form # 01: Confidentiality/conflict of interest agreement form

Appendix 2: Form # 02: Protocol submission form

Appendix 3: Form # 03: Protocol review assessment form

Appendix 4: Form # 04: Material Transfer Agreement (MTA) form