HUBERT KAIRUKI MEMORIAL UNIVERSITY

STANDARD OPERATING PROCEDURES (SOPs)

FOR

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

Prepared by the Institute of Postgraduate Studies and Research

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ACKNOWLEDGEMENT

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On behalf of IREC at HMKU, I wish to express my sincere gratitude to HKMU for its vision, which was the basis for the promulgation of the University's Research Policy which, in turn, led to the first edition of SOPs in 2005.

I would also like to sincerely thank the National Health Research Committee (a sub-committee of NIMR's MRCC) for receiving and thoroughly reviewing the drafts of our second Edition of SOPs from the very beginning. Indeed, the constructive criticisms and guidance given by the reviewers of the document enabled us to improve on and successfully complete the current version of SOPs.

Finally, I thank the Secretariat at HMKU for working tirelessly on the document, as was required by the National Health Research Ethics Committee (NatHREC). The Secretariat's commitment to the task it was assigned is reflected in the fine quality of the final product. IREC is heavily indebted to all those who have contributed to the successful production of the present edition of SOPs.

Prof Frederick Kaijage

Chairperson IREC, HKMU

ABBREVIATIONS

HKMU	Hubert Kairuki Memorial University
IREC	Institutional Research Ethics Committee
SOPs	Standard Operating Procedures
WHO	World Health Organization
TDR	Special WHO Programme for Tropical Diseases Research
FERCAP	Forum for Ethical Review Committees in Asian and Western Pacific Region
TEA	Tanzania Education Authority
NatHREC	National Health Research Ethics Committee
NIC	National Insurance Corporation
BICO	Bureau for Industrial Cooperation
CIOMS	Council for International Organizations of Medical Sciences
ICH	International Conference on Harmonization
IREC	Institutional Research Ethics Committee
EC	Ethical Clearance
ER	Ethical Review
DoH	Declaration of Helsinki

FOREWORD

Research is an inseparable part of university activities. Extending frontiers of knowledge through research is one of the attributes of a University. As a Medical University, HKMU conducts research through members of academic staff and students. Most of the studies conducted are Biomedical in nature, which invariably involve human participants. Because of human participation in clinical or field settings the University has to adhere to universal ethical guidelines, and more so to National Guidelines.

It is because of these facts that HKMU is striving to adhere to universal standards of conducting research so as to ensure that the results from these studies are accurate, and have scientific merit, and therefore credible.

Therefore, this Second Edition of the Standard Operating Procedures is a set of institutional guidelines to fulfil the goals of the University Research Policy. The SOPs are making reference to the international ethical guidelines namely CIOMS (2016), DoH (2013) and WHO (2000) and also to National documents, mainly: National Guidelines on Ethics for Health Research in Tanzania (2001), and NatHREC –SOPs (2014). The SOPs are a main guide to HKMU Institutional Research Ethics Committee (IREC) and others (researchers and reviewers alike) on all research processes.

It is my privilege to thank the National Health Research Ethics Committee for their advice as well as all others for their dedication and hard work towards completion of this document.

Prof. Charles S. Mgone
Vice Chancellor

INTRODUCTION

According to the WHO/TDR guidelines: "countries, institutions, and communities should strive to develop INSTITUTINAL ETHICS REVIEW COMMITTEES (IRECs) and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research" From this statement it becomes quite clear that "the purpose of an IREC in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants.

In order to achieve high quality ethical review, the IREC must always function according to written standards. TDR/WHO guidelines state that: "The IRB/IEC should perform its functions according to written operating procedures, should maintain written operating procedures, should maintain written records of its activities and minutes of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s)." The "written operating procedures" mentioned above are in essence the Standard Operating Procedures (SOPs) of an Ethical Review Committee.

Standard Operating Procedures (SOPs):
By definition these are detailed, written instructions to achieve uniformity of the performance of a specific function. If we are to look at the value and importance of SOPs for ethics review at the HKMU, we would categorically state that the need for objective and uniform specifications in reviewing a research protocol in accordance to international guidelines and requirements is only achievable when the ethics review system is guided by SOPs. This way, decisions of the IREC remain consistent.

In order for SOPs to have any meaning, one needs to have in place an institutionalized ethics review system that properly documents the very procedures. We have at the HKMU an ethics review system in the form of the IREC and a code to guide its functions. What we needed now were SOPs and guidelines for operationalisation.

SOPs should be easily tenable, simple to understand and apply, and subject to review. One of the cardinal guidelines is: "Principles and requirements in preparing a particular SOP and definitions of elements to be taken into account when an IREC is preparing a SOP". What this amounts to is that the IREC decides on relevant sets of guidelines from a wide range of national and international guidelines by WHO, FERCAP, TANHER, etc for writing its own SOPs. The national and international guidelines only give the framework.

Generally, the format of the FERCAP guided and TDR/WHO SOP has;

- An approval cover page
- Table of contents
- Purpose, scope, policy
- Responsibility
- Flow chart of activities.

We have been somehow flexible and not quite strictly followed the same format in formulating our SOPs for ease of application of this document and record keeping. This is in keeping with an

allowance provided by international codes and guidelines for formulation of SOPs, whereby a particular IREC may formulate SOPs in a way that suits its own circumstances and convenience provided that this is done while strictly observing international codes and guidelines; which is what we have done. We have also devised forms in compliance with each of the above SOP guidelines for proper record keeping in case of inspection and audit.

In general terms health research in Tanzania, just like in all other developing countries - and particularly in Africa - is increasing because of the numerous discoveries being made in the biomedical sciences worldwide along with new diagnostics procedures, drugs, vaccines and devices that need testing. Much as this is a positive development, the high disease burden, ignorance, poverty and weak regulatory organs and ethical review frameworks simply expose our people to abuse by researchers who may not be inclined to observing research ethics as stipulated in the international guidelines. The situation is even more compounded by limited awareness and knowledge among local health research scientists about the existence of such guidelines. It is against this background, therefore, that the establishment of national and institutional health research ethics review boards and committees becomes imperative.

International guidelines such as the Declaration of Helsinki, CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, WHO/TDR and ICH Guidelines for Good Clinical Practices outline ethical and scientific standards for biomedical research. Compliance with these guidelines helps to ensure that the dignity, rights, safety, confidentiality and well being of individual research participants are promoted and upheld and that the results of the study or trial being undertaken are credible and acceptable.

All international guidelines require ethical and scientific review of biomedical research, alongside informed consent and the appropriate protection of those unable to consent as essential measures to protect individual persons and communities who participate in biomedical research and related fields involving humans.

The purpose of this document, therefore, is to outline the process for authorizing, reviewing, archiving and amending SOPs for the IREC at the HKMU within the framework of our Ethical Guidelines. The standard operating procedures shall, as a matter of principle, be written in immediate future tense using active verbs. They shall be written in such a way that any end user unfamiliar with the procedures should be able to duplicate or apply the procedures accurately in a proper time sequence by following the document. At a closer look one will surely realize that the SOPs very well tie up and tally with the standard operating procedures recommended by the National Health Research Ethics Committee (NatHREC) of the Tanzania National Health Research Forum (TANHER-FORUM) whose mandate, among others, is to ensure harmonization of health research review guidelines and standard operating procedures in Tanzania.

VISION, MISSION AND FUNCTIONS

The Vision, Mission and functions of HKMU IREC are summarized below:

Vision of HKMU IREC

To become an IREC committed for protection of research participants.

Mission of HMKU IREC

The mission is to review, evaluate and decide on the ethical and scientific merits of the research protocols so as to guarantee the rights, safety, and protection of all individual research participants, community as well as researchers.

Functions of HMKU IREC

- Receiving protocols from Academic staff and students
- Reviewing the protocol/proposals
- Discussing the review comments and advising on the clearance
- Conforming to all monitoring procedures for research as stipulated in the SOPs

CHAPTER ONE

THE STANDARD OPERATING PROCEDURES (SOPs):

In this part of the document our Standard Operating Procedures (SOPs) within the framework of our IREC Ethical Guidelines for health research ethics review are being articulated with a view to give guidance to our Ethical Review Committee in its quest to protect and further the rights of the individual research participant while taking cognizance of the fact that relevant and viable health research is necessary and important for improving the welfare of humankind.

SOP 01: CONSTITUTING THE RESEARCH ETHICS REVIEW COMMITTEE

This SOP details procedures for constituting the IREC, its composition, terms of reference and scope. It also specifies conditions of appointing members to the Committee, resignation or disqualification and replacement.

(a) Composition of the Committee:

The Committee comprises 12 members who individually and collectively have the necessary qualifications and experience to review and evaluate the science, medical aspect, and ethics of research protocols presented to it for assessment. It is made up of both scientists and non-scientists from diverse backgrounds to undertake complete and adequate review of research proposals commonly received by the Institute of Postgraduate Studies and Research. At least two members of the Committee are medical practitioners, while we have on board one non-scientist (a lawyer by profession) representing the community, and some female members for gender equity.

(b) Terms of Reference of the Committee:

The Committee operates within specified Standard Operating Procedures (SOPs) which are detailed written instructions presented in a simplified format that describes all activities and actions to be undertaken by the IREC in order to achieve uniformity in its review of all protocols presented to it for ethical clearance. The purpose of the Standard Operating Procedures and their accompanying checklists and forms is just to simplify the organization and documentation of operation of the review process while maintaining a high standard of performance. Rather, SOPs enable and facilitate the ethical review process by setting standards and ensuring uniformity in decision-making and assure the public about the credibility and reliability of the IREC. SOPs promote transparency and efficiency in the communication process and simplify the day-to-day operations of the IREC.

The following are the terms of reference under which the Committee operates:

(1) To review within a reasonable timeframe health research proposals submitted to it and document its views in writing to the applicant(s); clearly naming/identifying the study, the documents reviewed and dates for the following:
   i. Approval for commencement of the study

ii. Modifications required prior to approval of the study
iii. Disapproval
iv. Termination/suspension of any prior approval.

(2) To safeguard the dignity, rights, safety and wellbeing of all study participants and communities by way of a thorough analysis of the science, rationale, ethics, etc of the intended study. Special attention shall be paid to studies that may include vulnerable participants.

(3) To request, as and when need arises, the investigator(s) to clarify any issue pertaining or related to the intended study or enlighten the Committee members on any aspect of the study but the researcher(s) / investigator(s) shall not participate in the deliberations of the Committee or in the voting of the Committee in any way on any issue.

(4) To obtain the following documents from investigator(s):

i. Summary of Protocol
ii. Study protocols(s) and / or amendment(s)
iii. Written informed consent forms and consent form updates that the investigator(s) propose to use in the study.
iv. Participant recruitment procedures
v. Written information about the intended study to be provided to would-be participants
vi. Available safety information
vii. Information about benefits available to would-be participants
viii. Research budget
ix. Curriculum vitae of the investigators/ researchers and the composition of the research team.

(5) To consider the suitability of the investigator(s) for the proposed study by considering the relevant qualifications, training background and experience as documented through updated CVs and/ or by any other relevant documentation.

(6) The Committee may request for additional information to what may be generally available from the investigator(s) if the members are of the opinion that additional information would assist them in making a balanced decision on the protocol or ensure greater protection of the rights, safety and / or wellbeing of would-be participants.

(7) To review both the amount and type of benefit/compensation to participants to ensure that such benefits/compensation do not present problems of coercion or undue influence on the study participants.

(8) The Committee will strictly and judiciously review the scientific and ethical merits of a submitted protocol for approval while executing the tasks thereby free from bias or influence from any quarter.

(9) The Committee essentially assists the investigator(s) in the protocol submission process. In this regard, the following items shall be made available to the members by the IREC Secretariat to facilitate the process:

(10)

i. Protocol submission forms and all relevant guidelines as per IREC Standard Operating Procedures (SOPs)
ii. Meeting almanac
iii. Committee membership list
iv. The IREC Ethical Guidelines

(11) The Committee members and consultant reviewers shall be provided by the IREC Secretariat with all relevant SOPs to guide them in the review process of all protocols submitted to them.

(c) Ethical Issues:

1. The Committee recognises that the protocols it approves may have previously been subjected to ethical review by other institutional/community review committees prior to submission to this Committee for implementation in specific localities.
2. In reviewing protocols and evaluating ethical issues, the IREC is aware of the diversity of laws, cultures and practices governing research and medical practices in various communities in Tanzania.
3. It by any means attempts to sufficiently inform itself, wherever possible, on the requirements and conditions of the various localities where the proposed study is being considered.
4. The IREC seeks to be informed, as appropriate, by institutional / community committees and researchers on the impact of the research it has approved.
5. The IREC is guided in its reflections, deliberations, and decisions by ethical principles and guidelines expressed in the Declaration of Helsinki (1964 and subsequent amendments, 2013), the International Ethical Guidelines for Biomedical Research Involving Human Participants (CIOMS ,2016), the Belmont Report, the European Convention on Human Rights and Biomedicine, WHO/TDR Guidelines, and national guidelines issued by the National Health Research Ethics Committee (NatHREC).
6. The IREC has composed its own SOPs basing on the Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO/TDR), the WHO & ICH Guidelines for Good Clinical Practice, FERCAP, and the Standard Operating Procedures of the National Health Research Ethics Committee (NatHREC).
7. The IREC seeks to fulfil and abide by all the requirements for international assurances, and is established and functions in accordance with the national ethical guidelines, laws, and regulations.

(d) Membership of the Committee:

1. The IREC operates as a subcommittee of the Senate Research and Publications Committee of the University and nomination of members to the Committee is made by the Vice Chancellor in his/her capacity as Chairperson of the Senate, subject to confirmation by the Senate.

2. Members are selected in their personal capacities, basing on their interest, ethical and scientific knowledge/background, and expertise as well as their commitment and willingness to volunteer their time and effort for the IREC's tasks and responsibilities.
3. Members are appointed for a period of 3 to 6 years, but this is entirely at the discretion of the appointing authority (the University Senate).
4. Membership may be renewed for up to two consecutive terms

(e) Conditions of Nomination to the IREC:

1. Willingness to publish their identity, name, profession and affiliations.
2. Willingness to sign a confidentiality agreement at the start of the term and a commitment to abide by the confidentiality agreement regarding meeting deliberations, applications, protocol submissions, information on research participants and related matters which they have had the privilege to know or access as a result of being members of the Committee. The confidentiality agreement protects the privacy, identity, and confidentiality of all parties whose information may be disclosed to the Committee in the course of its responsibilities and duties.
3. Readiness/willingness to disclose in writing any interest or involvement – financial, professional, or otherwise – in a project or proposal under consideration by the IREC.
4. Any member who has any vested interest in a proposal submitted to the IREC for review shall not participate in any deliberations related to the proposal.

(**f) Resignation, Disqualification, Replacement of Members from the IREC:**

i. Members may resign from their membership by submitting a letter of resignation to the Chairperson of the IREC, in which case the Senate will be informed for a replacement.
ii. Members may be disqualified from membership should the appointing authority provide written notification to the IREC and there is unanimous agreement among members of the Senate.
iii. The Senate shall request for a replacement of any member on the Committee under the following circumstances:
    (a) Protracted illness of a member which does not permit him/her to participate in the deliberations of the Committee.
    (b) Persistent absenteeism of a member without reasonable cause.
    (c) Voluntary withdrawal by a member.
    (d) Unethical conduct, such as continued breach of Confidentiality of Committee proceedings and matters.

SOP 02: ADMINISTRATION AND FUNCTIONS OF THE ETHICS REVIEW COMMITTEE

The purpose of this SOP is to describe the administration, office bearers, and the functioning of the IREC. It details the Secretariat, the functions of the Chairperson, the Secretary, the Committee, the Chair of the University Senate (VC), and dissolution of the Committee.

(a) The Secretariat and Officers:

1. The officers of the Committee shall be the Chairperson and Secretary.
2. The Chairperson shall be appointed from the external members of the Committee. The sitting Director of Postgraduate Studies and Research of the HKMU, will serve as Secretary to the Committee and the IREC shall operate as a subcommittee of the Research and Publications Committee of the University Senate. The members shall be appointed by the VC subject to confirmation by the Senate; and the Secretary shall be elected from among the appointed members of the Committee for each specific term and he/she shall, in all instances, be an employee of the HKMU.
3. The Chairperson shall be expected to be at the forefront regarding human rights and ethical issues; and he will, as a matter of principle, be expected to be well informed on regulations relevant to the use of human participants in health research.
4. The committee shall also have a Vice Chair person to take over in absence of the Chairperson.
5. The Committee shall have a permanent secretariat at the HKMU run by the Committee Secretary and administrative supporting staff.
6. The HKMU shall provide the necessary funding for the operations of the Committee.

(b) Functions of the Secretariat:

1. Organising an efficient and effective tracking procedure for each proposal submitted to the IREC for review
2. Prepare, maintain, and distribute study files
3. Organize Committee meetings regularly as per HKMU almanac
4. Prepare and maintain meeting agendas and minutes
5. Keep and maintain the Committee's documentation and archive
6. Communicate with the Committee members and applicants
7. Arrange for training of personnel and Committee members
8. Organise the preparation, review, revision and distribution of SOPs and guidelines.
9. Provide the necessary administrative support to the Chairperson in all activities relating to the IREC, such as communicating a decision to the applicant
10. Provide to the IREC updates on relevant and contemporary issues, including literature, related to ethics in health research

(c) Responsibilities of the Secretary to the IREC:

1. The Secretary shall be responsible for the custody of Committee documents, records and archives
2. Make a pre-review of each submission to the Committee to ensure adherence to administrative submission requirements
3. Undertake all administrative procedures in providing training and educational programmes to new and continuing IREC members on issues related to health research ethics. The training shall include, but not limited to, programmes

concerning basic principles of human participant protection, current literature and regulations/guidelines affecting the IREC.

4. Support the Chair in preparing and providing a statement of assurance when required by regulations guiding the establishment of the Committee.
5. Design and disseminate templates for Committee submission documents, including research protocols, informed consent materials, agreements and periodic and final reports.
6. Design and maintain a system for collecting and filing all Committee documents, including meeting minutes, member qualifications, protocol submission versions, deviations from approved protocols and periodic and final reports.
7. Assist the Senate to recruit new Committee members
8. Prepare and submit annual Committee operational budgets and plan to HKMU administration in consultation with the Chair.
9. Accept, verify, duplicate and distribute all submitted items to the IREC members for review; ensure that all required materials for submission are present and complete.
10. Create and distribute meeting agendas, and arrange meeting logistics.
11. Attend Committee meetings, take minutes during the meetings, and verify and distribute minutes in a timely manner.
12. Correspond with all submitting researchers at all times throughout the submission and review process, while remaining independent of the researcher's protocol operations; advise submitting investigators on preparing and submitting protocols for review according to relevant SOPs.
13. Properly distribute and keep files of all correspondences
14. Assist the Chair to conduct Committee meetings; continually study and update staff about Committee operational regulations.
15. Be available for and attend any external investigations or audits of the Committee.
16. Comply with requests during an investigation or audit.

(d) Functions of the Chairperson:

1. Chair Committee meetings in accordance with IREC regulations
2. Prepare and provide a statement of assurance when required by the regulations guiding the establishment of the Committee.
3. Facilitate the provision of training and educational programmes to new and continuing IREC members. The training shall include, but not limited to, programmes concerning basic principles of human participant protection, contemporary literature, regulations and guidelines affecting the Committee
4. Review and accept revisions made basing on Committee recommendations pending protocol approval.
5. Determine submissions that could be exempted from review, and notify the IREC and the submitting investigator of such exemptions.
6. Perform expedited review of research that meets the expedited review criteria
7. Assign responsibilities and duties to other IREC members in his or her absence.
8. Supervise the Secretary and ensure he/she is performing his /her tasks responsibly and efficiently

(e) Responsibilities of the Members of the Committee:

1. Review, discuss and consider research protocols submitted to the IREC for evaluation in order to safeguard the rights, safety, and well-being of study participants
2. Review progress reports and monitor ongoing studies as appropriate
3. Evaluate final reports and outcomes
4. Support the IREC executive in the discharge of their duties when asked to do so.
5. Maintain absolute confidentiality of all documents and deliberations of Committee meetings
6. Declare conflict of interest where applicable
7. Participate in continuing education activities in biomedical ethics and research
8. Undertake duties assigned to them by the Chair
9. Attend meetings regularly and participate actively during deliberations.

(f) Responsibility of the Chair of the Senate (VC):

1. He/she shall prepare and make a statement of assurance when required by the regulations guiding the establishment of the Committee
2. He/she shall ensure the provision of the necessary logistics and financial support for the smooth operations of the Committee.
3. If he/she has an interest in a particular protocol, he/she shall not take part in the reviewing process of that protocol.

(g) Dissolving the Committee:

1. At any point in time, should the institution cease to exist, the Committee is automatically dissolved.
2. The Senate, following written notification to each member, may also dissolve the Committee at any time.

SOP 03: COMMITTEE MEETINGS

This SOP describes the procedure for scheduling meetings, distribution of agendas and meeting procedures. Except for unavoidable circumstances, the Committee shall meet on the dates set in the HKMU almanac; using the HKMU Boardroom as the venue, unless otherwise stated. In some situations the Chairperson of the Committee may provide an alternative meeting date and venue, provided materials have been submitted for review.

1. A minimum of half the number of Committee members, including at least one non-scientific member and one medical scientist will form the quorum. If the protocol under review involves women as the target group, there must be a female member of the Committee present to form the quorum.
2. The Chair shall lead the meeting. In the absence of the Chairperson, the Deputy Chair or any other member of the Committee shall be asked by the Chairperson prior to his/her departure to lead the meeting.
3. The Secretary shall notify all Committee members of an impending meeting at least two weeks in advance by one of the following means: electronic mail, fax or carrier mail/messenger delivery.

4. The notification shall include a meeting agenda outlining all protocol and related research submissions for consideration at the meeting; materials, including copies of protocols, informed consent forms, continuing and final reviews, safety reports, etc.
5. In a situation where the Secretary has not been able to send the meeting materials to IREC members in time and the meeting is subsequently cancelled, the Secretary shall at once notify all the members of the cancellation and shall announce an alternative date of the meeting after consulting with the Chairperson. Whenever possible, the Secretary shall distribute meeting materials electronically.
6. The Secretary shall notify all Committee members of any changes in meeting time, date or agenda as soon as discovered.
7. Committee members shall keep an archive of all copies of meeting agendas and all other documents.

(a) Meeting Procedure:

1. The Chairperson, Deputy Chair, or a delegated member of the Committee shall call the meeting to order only when a quorum of the members is present. If a quorum is not realized, the meeting shall be rescheduled.
2. The Chairperson shall follow the agenda to conduct the meeting. He/she may, however, choose to deviate from the agenda based on personal judgement. The meeting shall most likely follow the following order:
    i. Adoption of the agenda
    ii. Confirmation of minutes of the previous meeting
    iii. Matters arising from previous minutes
    iv. Discussion of new agendas
    v. Action items (voting on protocols, acceptance of serious adverse events, periodic and annual reports, final reports, etc)
    vi. Any other business (AOB)

3. If the meeting is to review a newly submitted protocol, the principal investigator of that protocol may be invited by the IREC during deliberations on the protocol to answer questions or queries that may be raised by the IREC members but must go out when decisions are being made on the protocol.

(b) Minutes of the Meeting:

1. During Committee meetings, all deliberations shall be recorded either electronically or as written minutes of the meeting.
2. The minutes shall include a list of attendees, apologies and absentees, agenda items, matters arising from previous minutes and action taken by the Committee; decisions or vote on those matters, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving a research proposal; a written summary of the discussion of issues and their resolution.
3. The Secretary shall also include a summary of each considered protocol in the minutes.
4. The Secretary shall produce a hard copy of the minutes; he/she shall sign it and distribute it to all Committee members, along with a copy of the next meeting's agenda at least a week before the date of the subsequent meeting.

5. All Committee members shall read and review the minutes for accuracy and completeness.
6. The Committee members shall recommend the minutes to the next meeting as a true record of the previous meeting.
7. The Chairperson shall confirm the accuracy and completeness of the recommended minutes by signing them for archiving.
8. The Secretary shall archive the signed minutes together with the meeting's agenda and all relevant attachments.

SOP 04: PROTOCOL REVIEW PROCEDURE

This SOP describes procedures for submission and review of a protocol.

Management of Protocol Submission:

The Principal Investigator (PI) of a health research protocol shall submit to the Secretary of the IREC an application for assessment of a protocol following procedures outlined in this SOP by filling in an Application Assessment Form (Form HK/IREC 04 – 01)
; (Appendix 2). The Secretary shall be responsible for receiving and processing all new protocol submissions by filling in and signing Form HK/IREC 04 – 01A (Document Receipt Form; Appendix 1), a copy of which shall be given to the applicant; while ensuring that Form HK/IREC 04 – 01(Application Assessment Form; Appendix 2) is as well adequately filled in by the applicant and all elements required for consideration of the protocol are present.

(a) Details of Instruction:

1. The Principal Investigator (PI) shall submit a research protocol along with the following documents:
    i. Covering letter from the Chairperson of Department/Head of institution of affiliation, where applicable
    ii. Summary of the protocol
    iii. A full proposal pre-reviewed by a scientific committee from the department/affiliating institution with comments, where applicable.
    iv. Enrolments forms
    v. Questionnaires/other study instruments
    vi. Consent forms
    vii. Curriculum Vitae of investigators/researchers
    viii. Budget

2. Investigators must submit all documents at least three months prior to the commencement of the research study.
3. The Chair shall be responsible for determining whether a submitted protocol qualifies for expedited review.
4. Depending on the decision of the Chair on a particular protocol, three primary reviewers would be appointed to review the protocol.

(b) Participation of the Principal Investigator in Committee Meetings and Voting

Procedure:

SOP 04 sets conditions for participation of the Principal Investigator in the IREC meeting when his/her protocol is being reviewed.

Procedure:

1. The Secretary shall notify all PIs of the meeting scheduled to consider their submissions at least two weeks in advance. The Secretary shall also notify all PIs about their protocol's place in the agenda. A co-investigator/researcher may attend the meeting on the PI's behalf if necessary.
2. The PI may be invited into the meeting room during consideration of his/her protocol.
3. The PI may be invited to make a 15-20 minute presentation on the protocol being considered. After the presentation, the PI shall remain in the meeting room to answer any questions/queries, concerns and suggestions from IREC members.
4. After the question and answer session, the PI and any other attendees with a potential conflict of interest in the protocol shall leave the meeting as a decision or vote is being taken.
5. Each Committee member shall vote/have a say for or against a protocol or abstain. An absentee member is allowed to send in his/her comments on the protocol but cannot vote.
6. In order for a protocol to be approved, it shall receive the approval of a simple majority of those members present at the meeting. The Committee may also decide to postpone decisions on a protocol if more information or consideration is required.
7. If the Committee decides to disapprove a research proposal, the Committee shall include in its written notification to the investigator a statement of the reasons for its decision, and shall give the investigator an opportunity to respond in person or in writing.
8. After the Committee has voted on a protocol, the committee may invite the PI back into the meeting room for immediate notification of the voting results. The Committee may also decide to contact the PI by other means to communicate the results after the meeting.

(c) Assessment of a Study Protocol:

SOP 04 also details how the IREC will proceed in reviewing and assessing a protocol submitted for approval. The Application Assessment Form (Form HK/IREC 04 – 01; Appendix 2) is so designed as to properly structure the protocol review process and facilitate reporting, recommendation and comments. Essentially, SOP 04 applies to the assessment of all protocols submitted for review. The specific questions in the Application Assessment Form must be adequately addressed in the protocol itself and/or protocol-related documents under review. Relevant points made during discussion and deliberation on a specific protocol shall be recorded on the Application Assessment Form; so shall the decision reached by the Committee and the reasons for its decision.

It shall be the responsibility of the Secretariat/staff to record and file the decision, relevant points, and deliberations on a specific protocol including the reasons for the decision on the Application Assessment Form. The Chairperson of the IREC shall sign and date the form to approve the decision.

(i) Details of Instruction:

The Protocol indicated on the Application Assessment Form shall be summarized, recording general information about the protocol in the form (Form HK/IREC 04 - 01) such as the title of the protocol, protocol number and date, principal investigator(s) and co-investigator(s), funding agency/sponsor and project status - whether new/revised/rejected version, etc. Other information to be included in the summary shall be type of review required, whether regular, expedited or emergency; principal reviewer(s) from the Committee, brief summary of the study and comment by the Principal reviewer(s).

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

(iii) Qualification of investigators and study sites:
The qualifications of investigators shall be scrutinized to see whether their specialization and training background relate or tally with the demands of the study. The study sites shall also be examined for suitability of the study in terms of geographical distribution of the problem under study, facilities and infrastructure; accessibility, and availability of the study sites to accommodate the study. Disclosure of potential conflicts of interest shall also be examined.

(iv) Study Participation:
The IREC shall make an assessment with a view to evaluating voluntary, non-coercive recruitment of participation. The following aspects shall be assessed to see whether they have been adequately considered in the protocol:

i. Procedures for obtaining informed consent
ii. Content of the patient information sheet
iii. Content and language of the informed consent document
iv. Translation of the informed consent document into the local language
v. Simplicity and plainness of the language used in the documents for easy understanding by the general public.
vi. Contact persons with their addresses and telephone numbers
vii. Privacy and confidentiality
viii. Risks (physical, mental, social)
ix. Benefits to participants and to others
x. Compensation (reasonable / unreasonable)
xi. Involvement of vulnerable participants
xii. Provision for medical / psychosocial support
xiii. Treatment for study related injuries
xiv. Use of biological materials

(v) Examination of Community Involvement and Impact:

Ethical research conduct involving human participation requires community consultation; involvement of local researchers and institutions in the protocol design, analysis and publication of the results, development of local capacity for research where a foreign Principal Investigator (PI) is involved and is the main applicant. It also requires treatment, where there is need,

benefit to local communities, and availability of study results. The protocol shall be examined to assess whether there is adequate consideration of these aspects.

Where the IREC has sought expert opinion from a consultant on a protocol received for assessment, the consultant shall also use Form HK/IREC 04 – 01 (Appendix 2) in assessing the protocol, while he/she summarises his/her decision on a Summary of Decision of Review by Consultant(s) form (Form HK/IREC 04 – 03; Appendix 4)

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(vi)Decision Making by the Committee Members:

The guidance, advice and decision reached by the Committee members shall be summarised in a decision form (Form HK/IREC 04 – 02; Appendix 3). The summary shall include protocol title, date of review, checklist of documents reviewed, and decision reached by the Committee - such as approved / approved with recommendation/ recommended for resubmission after revision/disapproved or rejected. Recommendations and / or suggestions if any, including reasons for disapproving a study (if so), shall be part of the summary. The summary shall also include a list of all members participating in the review meeting.

(vii) Recording the Committee's Decision:

The Secretariat shall complete a decision form (Form HK/IREC 04 – 02; Appendix 3) and check the completeness and correctness of the assessment form. The Chairperson of the Committee shall sign and date the form, then a copy of the completed decision form shall be made while the original copy goes to the applicant. The copy of the decision form shall be kept in a file labelled, "Committee Decision" and the file put on an appropriate shelf.

CHAPTER TWO

SOP 05: PROTOCOL AMENDMENT PROCEDURE

The purpose of this SOP is to describe how protocol amendments are managed and reviewed by the IREC. The procedure applies to previously approved study protocols but are later amended by the investigators and re-submitted for approval by the IREC. Amendments made to previously approved protocols may not be implemented until reviewed and approved by the Committee. It shall be the responsibility of the Committee Secretariat to manage protocol amendments, as investigators may amend the contents of previously approved protocols from time to time. Protocol amendments must be submitted to the Committee for either "expedited" review or otherwise (see SOP 06).

(a) Details of Instruction:

1. The PI shall prepare the amendment package and submit it to the Secretariat of the IREC.
2. Upon receipt of the amendment package, the Secretariat shall follow the receiving procedures stipulated under Management of Protocol Submission (SOP 04) and Procedure for Maintaining Confidentiality of IREC Documents (SOP 09).
3. The application for amendment approval by the PI shall be made on an Amendment Submission Form (Form HK/IREC 05) and shall state / describe the amendment made, provide the reasons for the amendment, and clearly indicate the implications of the amendment - any untoward effects as a result of the amendment of the original protocol, for example; or expected benefits because of the amendment.
4. The Secretariat shall check the original Amendment Submission Form (Form HK/IREC 05) for completeness, presence of appropriate signatures, amended version of the protocol and appendix-related documents. Changes or modifications in the amended version shall be underlined or highlighted.
5. The Secretariat shall then:
    i. Notify the Chairperson of the Committee verbally and in writing about the amendment.
    ii. Keep all 'Sent' and 'Received' mail related to the notification of the Chairperson in the protocol file under the Correspondence section.
    iii. Send the request for amendment and the amended protocol, along with related documents, to the Chairperson within one working day of receipt by the Secretariat.
6. After review of the materials, the Chairperson shall determine whether the protocol requires expedited review or not. A protocol amendment which increases risks to study participants, as judged by the Chairperson, shall be scrutinized thoroughly and handled cautiously in areas such as a change in study design that may include but is not limited to:
    i. Additional treatment or deletion of treatment
    ii. Changes in inclusion / exclusion criteria
    iii. Change in the method of dosage application, such as from oral to intravenous use
    iv. Significant change in the number of subjects, if an increase or decrease is likely to substantially alter the fundamental characteristics of the study

v. Significant increase or decrease in dosage amount.

7. If the Chairperson decides the protocol requires full IREC approval, he/she shall indicate this decision on the checklist, sign and date the form.
8. If an amendment is received just before a scheduled Committee meeting; the Chairperson may decide to have the amendment reviewed by the full Committee at its sitting, even though the amendment may be expedited.
9. Upon receiving the recommendation from the Chairperson, the Secretariat shall:
    i. Place the protocol amendment request on the agenda for the next convened meeting and
    ii. Distribute to each Committee member documents containing the desired amendment while explicitly pointing out each change in the originally approved protocol; plus requested changes in the consent form, if applicable.
10. The process outlined in the Application Assessment Form (SOP 04) shall be used to review amended protocols and protocol-related documents.
11. The Chairperson shall call for a vote on the proposed amendments.
12. The Secretary shall note recommendations for changes to the protocol and /or informed consent requested by Committee members in the minutes and communicate the decision to the clinical trial office or Principal Investigator in writing.
13. If the Committee does not approve the protocol amendment, the notification to the investigator shall also state the reason for not approving the amendment.
14. If the IREC votes to demand modifications to any of the documents; the specific changes required shall also be communicated to the investigator, instructing him/her to make the necessary changes and resubmit the documents to the Committee for review.
15. The Chairperson shall complete and sign a decision form after the Committee has reached the decision.
16. The form and minutes of the meeting relevant to the discussion and decision reached shall be kept as an official record of the amendment review process.

(b) Verbal Communication and Preliminary Written Communication of the Decision and Completion of the Amendment Submission Form:

1. The Chairperson shall notify verbally the Principal Investigator about the decision reached as soon as possible after the review, but no later than seven working days following the review.
2. The Chairperson shall send a copy of the Amendment Submission Form with his/her signature and date of approval to the Secretariat within one working day after the review.
3. The Chairperson must sign and date the original version of this form and return this to the Secretariat within three working days after the review.
4. The Secretariat shall assign a unique ID letter that corresponds to the number of the amendment against the protocol number as an identification of the amended protocol.
5. The Secretariat shall send a copy of the signed and dated Amendment Submission Form to the PI within seven working days after approval.

6. The PI shall then provide a "clean" copy (underlining and highlighting the recommended/approved changes) of the protocol plus all protocol- related documents to the Secretariat for filing.
7. The Secretary shall place the original documents, the "clean" version of the amended protocol and all related documents in the protocol file.

SOP 06: EXPEDITED REVIEW PROCEDURE

The Standard Operating Procedure for expedited review is meant to give instructions on how expedited review shall be determined and carried out. The Chairperson, in collaboration with the Secretariat, shall determine which protocols may require expedited review and which ones may not. The following categories shall qualify to be considered for an expedited review:

1. Research activities that present no more than negligible/minimal risk to human subjects.
2. Minor changes in previously approved research protocol.
3. Modification/amendment of protocol
4. Protocol involves interviewing of non-confidential nature and not likely to harm the status or interest, or not likely to offend the sensibility of study participants.
5. Studies that involve collection of small amounts of biological specimens by non-invasive means (e.g. blood fluids, excreta, hair or nail in a non-disfiguring or threatening manner).
6. Collection of data for research purposes through non-invasive procedures (not involving general anaesthesia, sedation, venopuncture, etc) routinely used in clinical practice and applying medical devices approved for such use. Examples of such procedures include application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements.
7. Research involving data, documents or specimens that have been already collected or shall be collected for on going medical treatment or diagnosis.
8. Continuing review of a protocol previously approved with no modification to the original protocol; and studies have been conducted basing on the protocol, and no additional risk has been identified.

(a) Details of Instruction:

1. Expedited review shall be conducted by the Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the Committee in accordance with the requirements of protocol review. If the review involves a revised version, the selected members shall normally be those who reviewed the previous version of the protocol.
2. The expedited review shall be carried out on a complete study protocol with all required attachments as if it was being submitted for the first time
   (Form HK/IREC 04 -01). Results of the review process may be communicated to the PI before being discussed at a Committee meeting and reported retrospectively to the IREC as it convenes.

SOP 07: CONTINUING REVIEW PROCEDURE

The purpose of continuing review is to review progress of the entire study, not just changes made; so as to ensure continued protection of rights and welfare of research participants. The Chair and Committee members shall be responsible for determining whether the research is reviewed annually or more frequently, appropriate to the degree of risk. The Committee shall also be responsible for determining whether an independent Data and Safety Monitoring Board is required. The PI of the research shall be responsible for keeping the Committee informed on significant findings that affect the risk/benefit ratio and thus the need for more frequent review. The PI shall also be responsible for following the continuing review procedures and deadlines.

(a) Determination of Frequency of Continuing Review:

1. At the initial review of a research project, the Committee shall determine:
    i. How often it shall re-evaluate the project. All research shall be reviewed at intervals appropriate to the degree of risk, but not less than once per year and at least once before the end of the data collection stage.
    ii. 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.
    iii. Whether these studies need verification from sources other than the PI that no material changes in the approved research study have taken place or happened.

2. The PI shall use the Continuing Review Form (HK/IREC 07; Appendix 6) to complete the annual review report and shall include all required elements, including the following:
    i. Number and demographics of participants enrolled
    ii. Changes in principal and / or associate investigator(s)
    iii. A summary description of subject experiences
    iv. Any serious adverse events experienced
    v. Numbers of and reasons for withdrawals from the research
    vi. Research results obtained thus far.
    vii. A current risk-benefit assessment based on study results, and
    viii. Any new information since the IREC's last review.

3. If the investigator/researcher cannot provide any of the required information, he/she shall provide justification for the delay in the report, and a timetable for provision of the information. The investigator / researcher shall also submit a copy of the consent documents and procedures currently in use.
4. The investigator/researcher shall submit one hard copy of the continuing review report, with original signature. The investigator/researcher is also encouraged to submit an electronic copy of the review report via e-mail or disc.
5. Upon receipt of the continuing review report, the Secretary shall conduct a pre-committee review to ensure all the required elements are present. The Secretary shall work with the submitting investigator to ensure all elements are present before distribution of meeting items. The Secretary shall place the continuing review report on the next meeting's agenda.

6. The Chairperson may elect to invite an independent or alternate reviewer to the meeting. Committee members shall consider and vote upon all continuing review reports in a full meeting utilizing the protocol voting procedure. The risk/benefit ratio may change over time. The criteria the Committee uses to approve or disapprove continuation of research are the same as the criteria for approval of an initial research project.
7. The Committee 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 documents being used by the investigator/researcher have current Committee approval. After reassessment, the Committee may require that the research be modified or halted. The Committee may also impose special precautions or relax special requirements it had previously imposed on the research protocol. 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 investigator to notify the participants of these findings. The Secretary shall archive continuing review reports and supporting materials with the relevant meeting minutes.

(b) Timing of Continuing Review:

1. If the Committee has not reviewed and approved a research study by the study's current expiration date, IREC approval is considered to have expired and research activities should stop. No new subjects may be enrolled in the study. However, if the investigator/researcher is actively pursuing renewal with the Committee and the Committee believes that an over-riding safety concern or ethical issue is not involved, the Committee may permit the study to continue during the short time required to complete the review process.
2. If the investigator/researcher cannot provide any of the required information, the investigator/researcher shall provide justification for the delay in the report, and a timetable for provision of the information. The investigator/researcher shall also submit a copy of the consent documents and procedures currently in use.

SOP 08: CONFIDENTIALITY /CONFLICT OF INTEREST AGREEMENT

The purpose of this SOP is to provide some form of Confidentiality / Conflict of Interest Agreement; who should sign it, when and where to sign, and how the signed document should be kept. This SOP covers the Agreement on both Confidentiality and Conflict of Interest pertaining to activities of the IREC and information.

It shall be the responsibility of all newly appointed IREC members and Consultant Reviewers to read, understand, accept and sign the agreement stated in the Confidentiality / Conflict of Interest Form (Form HK/IREC 08: Appendix 7) before taking up their responsibilities with the IREC .They shall bind themselves to protecting the rights of the individual participant in any research project that comes under their review.

(a) Details of Instruction:

1. Newly appointed members or Consultant Reviewers shall:
    i. Obtain two copies of the Agreement Form (Form HK/IREC 08) from the Secretariat.
    ii. Read through the contents of the form very carefully, then fill in their names and addresses in the blank space provided thereby.
    iii. Ask questions, if any, and the Secretary or any other officer of the IREC shall explain or clarify the content.
    iv. Sign and date both copies and give the forms back for the Secretary to countersign and date.
    v. Keep a copy of the Agreement for their own record.

2. The Secretariat shall keep a copy of the signed Agreement in the IREC's Confidentiality / Conflict of Interest Agreement file which will, in turn, be kept in a secure cabinet with limited key holders and access.

SOP 09: MAINTAINING CONFIDENTIALITY OF IREC DOCUMENTS

The cause of violation of confidentiality is normally found in the day-to-day use of copies of original documents. This SOP, therefore, describes how to handle original documents and copies of documents in order to protect confidentiality of IREC documents. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, Committee documents, and correspondence with experts, auditors and the general public. It shall be mandatory to maintain absolute confidentiality of IREC documents and correspondence. It shall be the responsibility of all members of the Committee and staff of the Secretariat to enforce confidentiality.

(a) Details of Instruction:

1. Committee members:
Committee members and the Secretary who have signed a confidentiality agreement with the IREC at the beginning of their term of service shall have access to the confidential documents.

2. Confidential documents:
Confidential documents shall include documents reviewed by the IREC (protocols and their related documents, case report forms, informed consent documents, diary forms, scientific documents, expert opinion or reviews). They shall also include IREC documents (SOPs, meeting minutes, advice and decisions), correspondence (with experts, auditors, investigators, etc). Copies of documents, including draft and sequential versions, are considered to be confidential and should never be taken out except when a document is needed for day-to-day operations.

3. Authorization of acquisition of copies:
Only members of the IREC shall be allowed to ask for copies, and only staff members of the Secretarial shall be allowed to make such copies. The Secretary of the Committee may ask for help, but shall be responsible for maintaining confidentiality of all documents.

A log of copies (Form HK/IREC 09A; Appendix 8) shall be kept by the Secretariat. The log shall include: the name and signature of the individual receiving the copy; the initials of the member of the Secretariat who made the copy; the number of copies made and the date that the copies were made.

4. Copies Requested by Non-Members of the Committee:
If non-members of the Committee need copies of original documents, it shall be the responsibility of the Secretary to arrange for the copies and to maintain confidentiality of the copied documents. Copies made for non-members of the IREC shall be recorded in the Log of Copies of an original document.

5. Filing of Log of Copies:
The log of copies of an original document shall be stored with the original document. The log of copies shall not be a confidential document and can be reviewed upon request. A log of copies shall be maintained.

CHAPTER THREE

SOP 10: SELECTION OF AN INDEPENDENT CONSULTANT

The IREC may, from time to time, need consultancy or advice in its reflections on specific protocols, requests, or ethical issues from an independent advisor. The purpose of this SOP, therefore, is to provide guidance on procedures for engaging the expertise of a professional as a consultant to the Committee. If the Chairperson or Committee determines that a study shall involve procedures or information that is not within the area of competence or expertise of the Committee members, the Chairperson or the Committee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available on the Committee. It shall be the responsibility of the Secretariat to propose the name of the Consultant in consultation with the Chairperson.

(a) Details of Instruction:

1. Selection of an Independent Consultant:
The Secretariat shall choose a consultant to give study documents to review from a created roster of Consultants based on areas of expertise. The creation of the roster of experts shall involve the Secretariat conducting a qualification review of prospective consultants and making decision based on expertise, availability and independence criteria. The consultant shall provide to the Secretariat his/her Curriculum Vitae and confirm acceptance of his/her appointment in writing. These documents (the CV and a copy of his/her acceptance letter) shall be kept in a consultant file.

2. Consultation Services:
The Secretariat shall provide protocol packages to appropriate consultants. The consultant may either attend the meeting to participate in the review of the study as a non-voting member and/or may review the documents and prepare a consultant's report to be reviewed by the Committee in their regular meetings or extraordinary meetings. The consultant's report shall become a permanent part of the study file.

3. Termination of the Services:
Consultation services may be terminated by either the consultants themselves or the IREC. Upon termination of the consultant's services, the Secretariat shall ensure that all the qualifying documentation and the reason for discontinuation of the services are filed with the administrative documents.

SOP 11: REVIEW OF FINAL REPORTS PROCEDURE

The purpose of this SOP is to provide instructions on the review and appropriate follow-up of Final Reports for any study previously approved by the IREC. It shall be the responsibility of the IREC to demand a final report, which is part of an obligatory review process of every investigator's activities at the research sites while ensuring that all adverse experiences have been brought to appropriate resolution before termination of the study.

Although the IREC provides a Study Report Form (Form HK/IREC 11; Appendix 11) to the investigator, any mechanism (letter, form devised by the sponsor, etc) may be used, provided that the information submitted is sufficient. It shall be the responsibility of the Secretariat to review the report for completeness before making copies for review by the Committee meeting.

Detailed instructions:

1. Before each Committee meeting the Secretariat shall be guided by SOP 04 (Protocol Review Procedures) for receiving and checking the report packages. The Secretariat shall read the submitted report and give a briefing to the Chairperson before making copies and distributing it to all Committee members.

2. During the Committee meeting each Committee member shall review a copy of the final report before the meeting deliberates on it. The Chairperson shall invite a discussion on the study. Where necessary, a Committee member may call for a consensus on whether to request for further information or take action (if indicated) against the investigator before reaching a decision on the report. The Secretary shall record the proceedings and the decision taken by the Committee in the meeting minutes.

3. After the Committee meeting, the Secretariat shall notify the investigator of the decision taken. If no action is recommended by the Committee, the Secretary shall file the final report and the Committee shall consider the study as closed. The Secretary shall, in turn, have a copy of the final report signed by the Chairperson or designee and send an acknowledgement letter to the investigator then archive the study protocol and the report.

SOP 12: NON-COMPLIANCE/VIOLATION INTERVENTION

The purpose of this SOP is to provide instructions for maintaining records that identify investigators who fail to comply with IREC/national/international guidelines for the conduct of human research, or who fail to respond to IREC requests/queries. This SOP applies to all research projects involving human participants and approved by the IREC. The Secretariat shall be responsible for collecting and recording the non-Compliance List (Form HK/IREC 12; Appendix 12).

(a) Details of Instruction:

1. Whenever non-compliance has been noted, it shall be ensured that the investigator information is placed on the agenda of each Committee meeting.
2. A file shall be maintained that identifies investigators who are found to be in non-compliance with country regulations or who fail to respond to the Committee's requests/queries.
3. The Committee may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions shall be recorded in the minutes.
4. The Chairperson shall notify the investigator of the Committee's action in writing.
5. The Secretariat shall record the Committee's decision and draft a notification letter that shall be signed and dated by the Chairperson.

6. Four copies of the notification letter shall be made; the original shall be sent to the investigator, the second copy to the relevant National Authority, the third to the sponsor of the study or the sponsor's representative, and the fourth to the non-compliance file and stored on the shelf with an appropriate label.
7. The action shall be followed up after a reasonable time.

SOP 13: MONITORING AND EVALUATION OF SERIOUS ADVERSE EVENTS (SAE)

The purpose of this SOP is to provide instructions on the review and follow-up of reports of adverse and unexpected events in any active study approved by the Committee. Unanticipated risks are sometimes discovered during the course of a study. Information that may impact on the risk/benefit ratio must be promptly reported to, and reviewed by, the Committee to ensure adequate protection of the welfare of the study participants. This SOP applies to the review of SAEs and unexpected events reports submitted by investigators, DSMB, Local Safety Monitor, IREC and any other interested parties.

The primary responsibility of the IREC is to review and address SAEs and unexpected events with risks to subjects and/or others as well as complaints related to the ethics of the research study. In addition, the Committee is expected to offer mediation under appropriate circumstances while ensuring that researchers are well aware of the policies and procedures concerning reporting and continuing review requirements. The Secretariat shall be responsible for first screening and subsequently assessing the reports to see whether they need a review of the full Committee, Chairperson, other qualified Committee members or experts.

(a) Details of Instruction:

1. Before the IREC meeting:
The Secretariat shall review the reporter's assessment to determine whether the report requires review by the full Committee, the Chairperson or other qualified Committee member(s). Criteria of the review shall be as follows:

i. If assessment of adverse experience is unknown or unlikely, the report shall be forwarded to the Chairperson for review and determination if the full Committee should review the report at the following convened meeting.
ii. If assessment of adverse experience is possibly caused by, or probably caused by the investigational drug or study intervention, the Secretary should include the report in the meeting agenda for review at the following Committee meeting.
iii. If an adverse experience/investigational drug's safety report previously seen by the full Committee is being resubmitted by another investigator on the same study (as part of a multi- centre study), this notification shall not require full Committee review; instead it shall be reviewed by the Chairperson or some other qualified Committee member(s) and the Secretariat.

2. During the IREC meeting:
After reading and reviewing the report, the Chairperson or designee shall invite a discussion on the study and similar adverse experiences or events. Wherever appropriate, the Chairperson or another Committee member may call for a consensus on whether to:

i. Request an amendment to the protocol or consent form
ii. Request further information
iii. Suspend or terminate the study

3. If any of the above actions is taken, the Secretariat shall notify the investigator of the action taken. If the Committee takes no action, it shall be noted in the minutes. The Secretariat shall draft a formal letter to the investigator notifying him/her of the action he/she should take on the basis of the Committee's decision. The letter shall be signed by the Chairperson and the date of delivery shall be recorded.

SOP 14: DATA AND SAFETY MONITORING BOARD (DSMB)

In large studies or clinical trials, the IREC may also require a DSMB to be formed in order to keep the Committee informed on the balance between risks and benefits on a regular basis. In long-term trials, especially, the DSMB would review research data periodically to assess effectiveness and toxicity and decide if and when the data is sufficiently favourable to continued use of the treatment under study or discontinuation. The DSMB shall also decide whether adverse effects are serious enough to warrant termination of the study or clinical trial.

CHAPTER FOUR

SOP 15: PREPARATION AND MAINTENANCE OF STUDY FILES

The purpose of this SOP is to provide instructions on what to keep, and how to keep and maintain regarding study files. This SOP applies to all active study files that are maintained in the IREC office. It shall be the responsibility of the Secretariat and staff to ensure that all study files are kept securely for a specified period while facilitating retrieval at any given time. The storage place should be appropriately designed and structured, free from dust and moisture.

(a) Details of Instruction:

1. Storage of single-site study files:
   File folders shall be displayed with a blue tab to indicate the name of the sponsor of the study (company or otherwise), and a yellow tab to indicate the protocol number. Each folder of a single-site study shall be put into an appropriately labelled file with the following information:
   - i. Sponsor, protocol number, investigator's name and title
   - ii. Investigator's Brochure (drug trials)
   - iii. Initial Approval
   - iv. Revisions
   - v. Advertisements
   - vi. Adverse Experiences
   - vii. Correspondence
   - viii. Continuing Review, if applicable

2. Storage of multi-site study files:
   A Master File folder shall be displayed with a blue tab to indicate the name of the sponsor of the study (company or otherwise), and a yellow tab to indicate the protocol number. Each master file folder shall be put into an appropriately labelled file with the following information:
   - i. Sponsor, protocol number, project manager's name
   - ii. Investigator's Brochure (drug studies)
   - iii. Initial Approval
   - iv. Revisions
   - v. Advertisements
   - vi. Adverse Experiences
   - vii. Correspondence.

3. Storage of investigation files:

Each folder of an investigation protocol shall be put into a file with appropriate labelling as follows:

- (i) Sponsor, protocol number, investigator's name and title
- (ii) Initial Approval
- (iii) Revision
- (iv) Advertisements
- (v) Adverse Experiences
- (vi) Correspondence

(vii) Continuing Review, if applicable

4. Maintenance of study files:
   All study files shall be kept with the most present documentation filed on top throughout the course of the study. All closed study files shall be sent to an off-site storage facility and stored for at least 15 years after the end of the study. Archiving of files shall only be done after the IREC receives a final report of the study.

SOP 16: RESPONSE TO PARTICIPANT REQUESTS REGARDING RIGHTS

The IREC shall consider its prime responsibility to be assumption of the protection of the rights and welfare of human participants in a clinical trial or research study approved by its members. This SOP applies to all requests concerning the rights and well-being of the participants in all trials or studies approved by the IREC. This procedure shall provide guidelines for dealing with and accommodating requests from participants regarding their rights in any approved clinical trial or research study. It is the responsibility of all staff and Committee members acting on behalf of the IREC to deal with and sort out all participant requests within the scope of their responsibilities.

Informed Consent documents reviewed by the Committee may routinely contain the statement "Questions regarding the rights of a subject/participant/ patient may be addressed to the Chairperson (with an indication of address and/or telephone number)". Yet, on some occasions, the first contact a participant may have could be with just an IREC member or administrative staff. The IREC shall, as a matter of principle, designate the Chairperson as the person responsible for communicating with participants regarding their rights in a study or clinical trial. However, delegation of this responsibility to another IREC member or staff is acceptable provided this delegation is documented in writing. Delegation to non-committee members is not permitted.

(1) Handling a request:

(a) Upon receipt of an inquiry from a study participant, the IREC staff shall do the following:

(i) Record the request and information on Request Record Form (Form HK/IREC13)
(ii) Communicate with the Committee about the enquiry.
(iii) Refer the inquiry to the Chairperson in writing.
(iv) The Administrative staff may provide assistance in contacting the Chairperson, but shall not provide comments/opinions about the inquiry.

(b) The Chairperson shall document the communication for the Committee study file, seek follow-up information, provide advice as required, inform the IREC of the inquiry and follow-up at the next meeting; and delegate these tasks to the Secretary, who shall then do the following:

(i) Record information and any actions or follow-up taken in the Request Record Form (Form HK/IREC13)
(ii) Sign and date the form
(iii) Report to the Committee about the action taken and the outcome
(iv) File the request document, keep the record form in the "Response" file, and

(v) Store the file on the appropriately labelled shelf.

SOP 17: SITE MONITORING VISITS

The purpose of this SOP is to provide procedures on how and when a study site should be visited and monitored regarding its performance or Good Clinical Practice (GCP). This SOP applies to any visits and /or monitoring of any study sites as stated in the ERB approved protocol as to the place where the trial/study and/or laboratory tests being carried out will take place. It shall be the responsibility of the IREC to perform or designate some qualified agents to perform on its behalf on- site inspection of the research projects/studies/trials it has approved. The Secretariat, in consultation with the Chairperson, shall initiate an on-site evaluation of a study site for cause or for a routine audit.

(1) Details of Instruction:

(a) Selection of study sites:
The database files of the approved protocols shall be reviewed periodically. Study sites to be monitored shall be selected based on the following criteria:

(i) If the research project has never been approved by the IREC, a study visit should be planned within thirty days after the study starts.
(ii) Reports of remarkable serious adverse events
(iii) Number of studies the sites handle
(iv) Frequency of submission of protocols for IREC review.
(v) Cause audits
(vi) Failure to submit progress report or final report.
(vii) New sites.

(b) Preparing the Visit:
The IREC representatives shall notify the Principal Investigator within one week about plans of the visit. Meanwhile the visiting team shall make the appropriate travel arrangements, review the Committee files for the study and site, make appropriate notes, or copy some parts of the files for comparison with the site files.

(c) During the Visit:
The visiting team shall:

(i) Review the informed consent document to make sure that the site is using the most recent version.
(ii) Review 25% of the participant files to ensure that participants are signing the correct informed consent
(iii) Observe the informed consent process, if possible, and
(iv) Review the Committee files for the study to ensure that documentation is filed appropriately and confidentiality, everything is happening according to protocol.

(d) After the Visit:

The IREC representative(s) that made the visit shall:

(i) Write a report using the Checklist for a Monitoring Visit (HK/IREC/ 14) within two weeks, describing the findings during the audit.
(ii) Forward a copy of the site visit to the site-monitoring file for full Committee review.
(iii) Send a copy of the report to the site for their files.
(iv) Place the report in the correct site files.

(e) Presenting the inspection results to the full Committee:

(i) The presentation shall be scheduled in a meeting agenda and presented to the next meeting of the IREC.

SOP 18: COMMUNICATION RECORDS

The purpose of this SOP is to ensure proper completion, distribution and filing of verbal and written communications and other study-related or process-related information with investigators, sponsors, volunteer participants, institutes, etc. This SOP applies to all communication activities related to trials/studies under the approval of the IREC.

Details of Instruction:

1. Individuals may utilize different communication recording mechanisms; they may be handwritten, typed or computer-generated communications.
2. The written record shall contain, but not limited to, the following: date of communication, study information (e.g. sponsor, protocol number, investigator), name of person contacted, contact address, telephone number, e-mail address, summary of the communication made, notation of any follow-up necessary and signature of individual making the record.
3. Upon completion of the record, the individual shall distribute copies as appropriate for filing.

SOP 19: MANAGEMENT OF PROTOCOL TERMINATION

This procedure describes how protocol termination is to be managed by the IREC. Protocols are usually terminated at the request/recommendation of the Scientific Director or the Chair of the applying institute's ethics committee or board where applicable, the Data and Safety Monitoring Board (DSMB), or any other authorized body when participant enrollment and follow-up are discontinued before the schedule time. This SOP applies to any protocols approved by the IREC. It shall be the responsibility of the IREC Chairperson to terminate any protocol in the interest of study participants' safety, health, or welfare. The Secretariat shall be responsible for management of the termination process.

Details of Instruction:

1. Upon receipt of a recommendation for protocol termination the Secretariat shall verify the contents of the package for inclusion of the following before dating:

    (i) Request for Termination Memorandum (Form HK/IREC 15; Appendix 15).
    (ii) A brief written summary of the protocol, its results, and accruing data.

(iii) Original Continuing Review Application Form (Form HK/IREC 07)
(iii) Under "Action Recommendation" termination should be indicated.
(iv) Completeness of the remainder of the information, including accruing data since the time of the last continuing review.
(v) Presence of the required signatures (applying institute's Scientific Director, ethical review body's Chair, etc if applicable).

2. The Secretariat shall notify the Chairperson regarding the request for protocol termination by sending a copy of the termination package to the Chairperson within one working day upon receipt of the termination request. The Chairperson shall review the results, reasons and accruing data and call an emergency meeting of the IREC.

3. The Chairperson shall sign and date the Continuing Review Application Form in acknowledgement and approval of the termination and return the form to the Secretariat within five working days of receipt of the package, who shall then do the following:

(i) Review, sign, and date the Continuing Review Application Form indicating that the termination process is complete.
(ii) Make a copy of the completed Continuing Review Application Form and send it to the PI for their records within seven working days.
(iii) Store and inactivate the protocol documents.
(iv) Keep the original version of the termination memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file.
(v) Send the file to archive and store the file indefinitely.
(vi) Place the protocol and related documents into the inactive protocol folder on the shelf in the following directory: F:\document\inactive protocols.

CHAPTER FIVE

SOP 20: AUDITING AND NSPECTION OF COMMITTEE IREC

The purpose of this SOP is to give guidance on how to prepare for an audit or inspection of IREC activities. This procedure applies to every unit of the IREC office. It is the responsibility of the Secretariat, members, Chairperson and administrative staff of the IREC to perform their tasks and duties according to laid down Standard Operating Procedures and should, for that matter, be always prepared and available to answer questions during evaluation, audit or inspection visits of their activities by authorities or guests.

Details of Instruction:

1. Upon receipt of a notice of inspection visit, the Chairperson shall inform the Secretariat and alert every unit of the IREC to prepare for the visit. The Secretariat shall go through all steps in a Checklist of Audit and Inspection (Form HK/IREC 16; Appendix 16) and note/comment on each part while emphasizing on studies with problems. Specifically, the following shall be done or revisited in preparation for the inspection:

(i) Check if all documents are labeled and kept in the right order for an easy and quick search.
(ii) Check for any missing or disorganized records
(iii) Background and training records of IREC members
(iv) Application Submission Records
(v) Communication Records
(vi) Amendment Approval
(vii) Meeting Agendas, Minutes, Action letters
(viii) Active files
(ix) Continuing and Final reports
(x) Meeting room and all other facilities.
(xi) Review the SOPs.
(xii) Make sure that no omission or deviation exists.
(xiii) Make sure there are good reasons for any omission or deviation
(xiv) Inform Committee members about the inspection date and find out if they are able to attend the audit/inspection meeting.

2. Upon arrival of the Auditor(s)/Inspector(s), the Chairperson or the Secretariat shall welcome and accompanies the auditors/inspectors to the reserved meeting room. Members and some key staff shall also be present in the meeting room. The conversation shall start with the auditor(s) / inspector(s) stating the purpose of the visit and what kind of information and data they would need. The Chairman/designated spokesperson of the Committee shall answer questions of the auditors/inspectors clearly, politely and trustfully with confidence and straight to the points. All information and files shall be made available as requested by the auditors/inspectors.
3. After the auditor(s) / inspector(s) have left, the Chairperson shall call for correction of any mistakes pointed out by the audit(s) and internal follow-up audit shall be carried out. A report shall be written and get approval from the Chairperson. Appropriate time for correction and

improvement process shall be allowed and an outcome of the audit process shall be evaluated. The record of the report on the audit/inspection meeting shall be kept in the audit/inspection file and record of findings from the internal follow-up audit in the internal audit file.

SOP 21: DISTRIBUTION OF SOPs AND GUIDELINES

This SOP describes how to handle, distribute, and control the distribution of the IREC approved SOPs and Guidelines. The IREC functions according to internal rules as laid out in its written SOPs. The SOPs, guidelines, and the documents thereby are property of the institute and shall be kept confidential in a safe and secure place. They shall under no circumstances be disclosed to anyone without written permission from the IREC. However, for the sake of maintaining a candid and transparent relationship with non-members of the IREC such as the public, client, or any other interested parties; certain procedures, documents, and guidelines could be disclosed or availed to non-members provided a confidentiality agreement under SOP 09 (Standard Operating Procedure for Maintaining Confidentiality of Ethics Committee Documents) is signed by the interested party.

SOP 20 sets the premises and boundaries for the distribution of SOPs, guidelines, and maintenance of the log of distribution. It is the responsibility of the IREC Secretariat or designated individuals to follow the institute's policy, methods, format and system when distributing any SOP or Guideline of the IREC.

Details of Instruction:

1. The Secretary shall distribute the SOP to all Committee members, archive the electronic and hard copy, and update the indexed list of SOPs. All requests for extra copies may be made to and fulfilled by the Secretary.

2. Two distribution logs, one for the SOP (Form HK/IREC 09A; Appendix 8) and another for guidelines (Form HK/IREC 17A; Appendix 17), shall be kept. Separate forms shall be used for recording distribution of each SOP (Form HK/IREC 17B; Appendix 18) and each guideline (Form HK/IREC 17C; Appendix 19).

3. A table of information required shall be made and shall include index number, name of recipient, institute that the recipient belongs to, code number of the SOP or guideline, number of copies taken, signature of the recipient, and date taken. Sufficient copies of the forms as specified in the inventory log shall be made.

4. The forms (Form HK/IREC 09A and Form HK/IREC17) shall be placed in specific and properly labeled files and placed in an appropriate shelf.

5. A list of names of all IREC members and administrative staff to whom the SOP shall be given shall be listed in the distribution section of the approval cover page (Form HK/IREC 17D; Appendix 20) of each master SOP. The name and the relevant code of the SOP being disseminated to the interested party shall be filled in the distribution log form.

6. The tally of each SOP to be copied shall be made and recorded in an inventory log (Form HK/IREC 17B; Appendix 18). Sufficient copies of every page of the master SOP for everyone in the Committee shall be made and bound in a loose copy/handout in the correct sequence for ease of location by the members.

7. Copies of each SOP/Guideline for every recipient shall be made, and the original copy shall be kept as a master SOP in a file labeled "Master SOPs". The "Master SOPs" file shall be kept in a secure cabinet with a lock and key, and the key shall be kept by the IREC Chairperson or Secretary.

8. A delivery form shall be filled in and Committee members shall be notified on the number of copies of the SOPs/Guidelines delivered to every recipient. The recipient shall sign a log form (Forms HK/IREC 09A and 17) as proof of reception. The distribution log shall be filed and the file returned to the appropriate shelf.

9. The names and code numbers of SOPs or Guidelines copied or distributed to anyone shall be kept and recorded in an appropriate inventory log (Forms HK/IREC 09AB and 17C; Appendix 19) and the inventory log file returned to its shelf.

SOP 22: ARCHIVING OF STANDARD OPERATING PROCEDURES

The purpose of this SOP is to provide instructions for storing inactive study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors. The files and documents are retained for at least three years after completion of the research study so that the records are easily accessible to auditors and inspectors. Copying of files and documents for or by authorized representatives of national authorities when required is allowed.

(1) Maintenance and retrieval of archived documents:

(a) Maintenance and retrieval of files and documents from the archive shall be the responsibility of the Secretary. After receiving the final report, the Committee members shall review the final report. The Secretary shall then do the following:

(i) Remove the contents of the entire study file from the active study filing
(ii) Verify that all the documents are present in organized manner.
(iii) Obtain an archive number from the Archive Department and enter the number into the data base.
(iv) Place the file in a storage container.
(v) Send it to the appropriate storage facility.
(vi) Hold the files of multi-study centres until all the study centres are closed then place the files in a storage container together and archive.

2. For archiving administrative documents, an administrative staff of the Secretariat shall prepare inventories of miscellaneous administrative documents, place the documents in an appropriate storage container which will subsequently be sent to the appropriate storage facility. In retrieving documents the Secretary shall maintain confidentiality as stipulated in SOP 09 (Procedure for Maintaining Confidentiality of Ethical Review Committee Documents).

3. Retrieval of documents shall only be done with a Document Request Form (Form HK/IREC 18; Appendix 21) signed and dated by the Chairperson. The person requesting for the retrieval of a document/file shall also sign and date the request form. The administrative staff shall retrieve archived documents in accordance with approved procedures of the Archives department. The retrieved file shall be returned to its place after its use and a dated and signed record about its return shall be kept.

SOP 23: REVISION OF SOPs

The purpose of this SOP is to give guidelines on when and how SOPs shall be reviewed.

If the IREC wishes to revise or update an SOP, this is how it will proceed:

1. It shall request an electronic copy of the document from the Secretary, or may request minor changes to be made directly by the Secretary.

2. The SOP shall be evaluated for accuracy and timeliness in an annual review and the Secretary shall alert the Committee of an annual review requirement.

3. The IREC, Secretary, or an assigned reviewer shall ensure that the SOP reflects the most current outline of procedures. If the document does not need revision, the author shall return the document to the Secretary for recording and filing.

SOP 24: EMERGENCY MEETING

The purposes of this SOP are:

1. To give guidelines on the process of preparing an emergency meeting.
2. To provide instructions on the review and approval of study activities using the Emergency Meeting Procedure

This SOP applies to emergency IREC meetings

(a) Details of Instruction:

(i) Emergency meetings may be scheduled to review/approve new studies, additional investigators, continuing review, protocol amendments and other study activities that require full Committee review.
(ii) For routine health research studies, an expert in the field chosen by the Chairperson shall be in attendance at the meeting.
(iii) A quorum here shall be necessary; all members of the Committee shall be informed about the decision made.
(iv) It shall be the responsibility of the Secretariat and the Chairperson to decide whether an emergency meeting should be called.
(v) Every Committee member has to confirm his attendance before the emergency meeting.
(vi) Before the IREC meeting:

(a) The IREC administrative staff and Secretariat shall decide to call an emergency meeting based on the following criteria – urgent issues, if delay will affect or

have impact on public benefit; occurrence of unexpected serious adverse events; it is a matter of life and death; other appropriate reasons.

(b) The Secretariat shall contact all members, if possible, or at least three members to participate in the meeting where all members cannot be contactable; but, then, the Committee should later be informed about the decision.

(c) The Secretariat shall prepare packages for the meeting

(d) Emergency meetings may also be held via a teleconference where it is feasible.

(vii) During the meeting:

Follow the related SOPs;.eg, Management of Protocol Submission, Expedited Review, Review of Protocol Amendments, etc.

(viii) After the meeting:

Follow the related SOPs.

CHAPTER SIX

SOP 25: GLOSSARY OF TERMS AND DEFINITIONS

This SOP is designed to collect, standardize and define terms, abbreviations, phrases, titles of the HKMU Institutional Ethics Review Committee (IREC) and its administrators in order to facilitate the use and understanding of the SOPs.

The definitions are divided into two sections, namely: (a) descriptions/definitions of personnel and subjects (b) terms, abbreviations and phrases as used in the Committee SOPs.

This SOP applies to all persons preparing and using the SOPs. It is the responsibility of the Secretariat, Members of the Committee and the Chairperson to define or determine the appropriateness of the description or definition.

(a) **Description of titles of personnel:**

Titles	Description
Administrative Staff	They are IREC staff responsible for the day-to-day administrative functions and duties of the IREC; they support activities and responsibilities of the Committee members.
Chairperson	A member of the Committee presiding over IREC meetings, assisted by the Deputy Chairperson. He/she is responsible for expedited approvals on behalf of the Committee.
Clients	As an institutional ethical review committee, the IREC considers investigators, investigational sites, sponsors or sponsor representatives as its clients or customers. Clients requesting the services of the IREC are asked to accept and abide by the procedures set forth in these documents.
Committee Members	Non-employee individuals serving as regular and alternate members of the IREC. This Committee is constituted in accordance with the IREC membership requirements set forth in SOP 01. Individuals qualified to vote at a duly convened IREC meeting (SOP 01 – Committee Membership: Selection and Replacement).
Ethical Review Committee	Its responsibility is to ensure the protection of rights, safety and well being of human participants involved in biomedical research; and to provide public assurance of that protection.
Project Manager	Individual responsible for coordinating an investigational study.
Senior Administrative Staff	Titles include IREC Supervisor, Administrative Coordinator, Secretary.
Site Coordinator	The person at the study site who is responsible for managing the study. This person can also be referred to as a Project Manager.
SOP Committee	A selected committee of IREC members and administrative staff who oversee the preparation, review, and periodic revision of the SOPs.
The Committee	This comprises at least five regular members and alternate members who may serve as equals within the Committee. The

	composition of the membership must reflect a diversity of backgrounds sufficient to assure: i. Expertise and experience to provide adequate review of research activities, consideration of race, gender, and cultural backgrounds. ii. Sensitivity to attitudes and concerns of the community and to the participant population. iii. Knowledge of applicable regulation, laws and standards of professional conduct and practice. iv. No member is participating in the initial or continuing review of any project in which he/she has a conflict of interest. v. No gender discrimination. The Committee is established to review and monitor biomedical research involving human participants. The primary purpose of such review is protection of the rights and welfare of the human participants. In accordance with national and international codes, laws, regulations, and statutes; the IREC has the authority to approve, require modifications to, or disapprove research.
Active Study Files	Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the IREC.
Addition/Correction of terms	Members are encouraged to propose any additional terms or make correction of any terms defined in this SOP at any time. If, for some reason, they feel a clarification should be made; they are encouraged to write their proposal and submit it to the Secretariat for action.
Administrative Documents	These include official minutes of the Committee meetings as described in SOP 09; the SOPs; historical files and Master Files as described in SOP 22; Distribution, Implementation and File Maintenance.
Adverse Event	An adverse event is any undesirable experience associated with the use of a medical product by a patient.
Amendment protocol package	A package of the amended parts and related documents of the protocol previously approved by the IREC but later changed after the study had been going on for some time.
Clinical trial office	An institute or office where an approved study is taking place, and where the principal investigator can be reached.
Application Assessment Form	An official record that documents the protocol review process.
Approval of the addendum	An official record that documents the review process of an addendum.
Audit	A systematic and independent examination of research study/trial approval activities of the IREC to determine whether the review and approval processes are properly conducted; and the documents and data are kept, recorded and reported according to

	the SOPs, GCP, international codes such as the Declaration of Helsinki and applicable regulatory requirements.
Committee Representatives	The IREC may, for some reasons beyond its control, rarely find time to perform site monitoring visits itself. It may then ask external experts or other ethics committees to do the task on their behalf and later report their findings to the IREC.
Confidentiality	Prevention of disclosure to people other than authorized individuals of Committee information and documents
Conflict of Interest	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 three key elements in this definition: financial interest; official interest; and professional interest. A conflict of interest occurs when: i) An individual's private interest differs from his or her professional obligations to the institute. ii) Professional actions or decisions occur which an independent observer might reasonably question. A conflict depends on a situation and not necessarily on the character or actions of the individual. Potential conflicts of interest must always be disclosed and managed as per IREC procedures.
Deviation	Any instance in which a current research protocol approved in accordance with an IREC SOP cannot be or has not been followed.
Document	Paper documents, electronic mail (e-mail), faxes, audio or video tapes.
Documents to be delivered	Any Documents, electronic mail (e-mail), faxes, audio or video tapes.
Expedited approval	A Committee's approval granted only by the Chairperson of the Committee or designated member for minor changes made to current approved research protocol or activities and for research which involves no more risks than minimal risk.
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 the protocol and for research that pose minimal risk to participants.
Final Report	An obligatory review of study activities presented as a written report to the Committee after the last participant has completed all visits and all adverse experiences have been brought to appropriate resolution.
Guideline	Advice or information given in order to perform certain tasks
Inactive study files	Supporting and approved documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records, communications and correspondence with the investigator or reports (including but not limited to Continuing Review Reports, Safety Reports, reports of injuries to participants, scientific evaluations) that correspond to every study approved by the IREC for which a final report has been reviewed and accepted.

Independent consultant	An expert who gives advice, comments, and suggestions during review of study protocols but has no affiliation to institutions or investigators tendering research protocols for review.
Inspection	The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and / or contract research organization's (CRO) facilities, office of ethics committees, or at other establishments deemed appropriate by the regulatory authority.
Investigational files	A file keeping research protocols that are under investigation or relate to an on-going study.
Investigational Medical Device	A medical device which is the object of clinical research to determine its safety or effectiveness.
Investigational New Drug	Investigational new drug means a new drug, antibiotic drug, or biological drug that is used in a clinical investigation. The term also includes a biological product that is used *in vitro* for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part.
Master file	A file for storage of originally signed and dated documents.
Master SOP files	An official collection of IREC standard operating procedures (SOPs) accessible to all supporting staff, IREC members, auditors and authorities or government inspectors as a paper version with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of SOPs cannot be considered official.
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, for example pregnancy.
Minutes	The official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) IREC review meeting. The minutes identify fully each protocol and /or activity and record the outcomes of each voting action. The IREC votes separately on each collective set or each item submitted for review: protocol, consent form, investigator, advertisement(s), etc. 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 IREC or its representatives take by visiting a study/trial site to assess how well the investigators and applicant institutes are conducting researches, taking care of study/trial participants by recording data and reporting their observations,

	especially serious adverse events noted during the study or trial. A monitoring visit shall normally be arranged in advance with the principal investigators.
National Health Research Ethics Review Committee	An independent national ethics review committee for Tanzania.
New Study	A study protocol including informed consent, investigator's qualifications, information on a drug or device and advertisements (if applicable) presented to the Committee for approval for the first time and not previously approved by the Committee. This includes re-application for those studies previously 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 national and international codes and regulations; or who fail to respond to the IREC's requests, thus giving justification and reason for termination of the study.
Non-significant Risk Device(NSR)	A non-significant risk device is an investigational device that does not pose a significant risk to research participants.
Nutrient Supplements	Substances which are necessary for the body's nutritional and metabolic requirements/processes.
Participants' rights	It is essential that human rights are protected through strict observation by the IREC of the principles of the rule of law. Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family shall be central in all IREC activities while discharging their duties to the public.
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 with the Secretariat sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the Committee.
Protocol Amendment	A change to the study protocol during the planning or course of the trial. The amendment is a foreseen change to the study plan that requires formal approval by the sponsor and IREC.
Quorum	Attendance at any convened meeting of the board where three of the regular (or alternate) members, including at least one physician and one layperson, is maintained throughout the discussions and voting portions of the meeting.
Scientist	Professionals with either biomedical or non-biomedical backgrounds.
Serious Adverse Event (SAE)	The adverse event is SERIOUS and should be reported when the patient outcome is: **Death** – Report if the patient's death is suspected as being a direct outcome of the adverse event. **Life – Threatening** – Report if the patient was at 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. Examples: Pacemaker failure; gastrointestinal haemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing. **Hospitalization** (initial or prolonged) – Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. Examples: Anaphylaxis psuedomembranous colitis or bleeding causing or prolonging hospitalization. **Disability** – Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity, Peripheral neuropathy. **Congenital Abnormality**– Report if there is suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. Examples: Vaginal cancer in female off spring from diethylstilböestrol during pregnancy, malformation in the offspring caused by thalidomide, etc. **Requires Intervention to Prevent Permanent Impairment or Damage** – Report if it is suspected that the use of a medical product may result in a condition which requires medical or surgical intervention to preclude permanent impairment or damage to a patient. 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.
Significant Risk Device (SRD)	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 a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the participant, 3) is for some use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impingent of human health, safety, or welfare of the subject, or 4) presents a potential for serious risk to the health, safety, or welfare of the participant.
Standard Operating Procedures (SOP)	Detailed written instructions in a certain format describing activities and actions undertaken by an organization to achieve uniformity in the performance of a specific function.
Stipulation	Putting forward as a necessary condition
Vulnerable Participants	A vulnerable category of participants includes children, prisoners, pregnant women, handicapped or mentally disabled persons, and economically or educationally disadvantaged persons who are likely to be vulnerable to coercion or undue influence.

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CHAPTER SEVEN

APPENDICIES

APPENDIX 1 FORM HK/IREC 04 – 01A DOCUMENT RECEIPT FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

FORM HK/IREC 04 – 01A
APPENDIX 1

DOCUMENT RECEIPT FORM

Name of Investigator	Proposal title	Date	Name of the Recipient	Signature

APPENDIX 2 FORM HK/IREC 04 – 01 APPLICATION ASSESSMENT FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

APPLICATION SUBMISSION

FORM HK/IREC 04 - 01: APPLICATION ASSESSMENT FORM APPENDIX 2

Title of protocol:	Protocol No: ……	Date…….
Principal investigator:		
Co-Investigators:	1. 2. 3 4 5 6 7	
Total no. of study participants:		
Funding agency:		
Review status:	Initial [ ] Resubmission [ ] Amendment [ ] Termination [ ]	
Principal reviewer(s)	1 2 3 4 5	
Project status:	Single site [ ] Multiple study site [ ]	
The study in brief:		
Study design:	Simple randomized [ ] Stratified randomized [ ] Single blind [ ] Double blind [ ] Triple blind [ ] Placebo controlled [ ] Compare with standard treatment [ ] Cross-over [ ] Parallel [ ]	
Objectives of the study:	1 2 3 4 5 6 7 8 9	

	10
Methodology:	
Objectives of the study:	Clear [ ] Not clear [ ] What should be improved
Need for human participants	Yes [ ] No [ ] Comment:
Methodology:	Clear [ ] Not clear [ ] What should be improved?
Background information:	Clear [ ] Not clear [ ] Comment:
Risk/benefit ratio assessment:	Fair [ ] Unfair [ ] Comment:
Sampling frame size:	Okay [ ] Not okay [ ] Comment:
Sample calculation:	Okay [ ] Not okay [ ] Comment:
Sampling method:	Okay [ ] Not okay [ ] Comment:
Sample size:	Adequate [ ] Not adequate [ ] Comment:
Inclusion criteria:	Okay [ ] Not okay [ ] Comment:
Exclusion criteria:	Okay [ ] Not okay [ ] Comment:

Withdrawal criteria:	Okay [ ] Not okay [ ] Comment:
Involvement of vulnerable participants:	Yes [ ] No [ ] Comment:
Procedures of recruitment of participants:	Okay [ ] Not okay [ ] Comment:
Control arms if applicable:	Yes [ ] No [ ] Comment:
CV of investigators:	Qualified [ ] Not qualified [ ] Comment:
Disclosure of potential conflicts:	Yes [ ] No [ ] Comment:
Facilities and infrastructure of participating sites (institutions):	Appropriate [ ] Adequate [ ] Not appropriate/adequate [ ] Comment:
Community consultation:	Yes [ ] No [ ] Comment:

Involvement of local researchers and institutions in protocol design, data collection, analysis and publication of results:	Yes [ ] No [ ] Comment:
Contribution to development of local human and physical institutional infrastructure/capacity building for research:	Yes [ ] No [ ] Comment:
Availability of study results to local community:	Yes [ ] No [ ] Comment:

Benefits of study to local community:	Yes [ ] No [ ] Comment:
Voluntary, non-coercive (inducement) Recruitment/participation:	Yes [ ] No [ ] Comment:
Procedures of obtaining informed consent	Appropriate [ ] Not appropriate [ ] Comment:
Contents of the informed consent:	Adequate/clear [ ] Not adequate/clear [ ] Comment:
Language of the informed consent document	Appropriate/clear [ ] Not appropriate/clear [ ] Comment:
Contact persons for participants	Appropriate/clear [ ] Not appropriate/clear [ ] Comment:
Privacy and confidentiality	Yes [ ] No [ ] Comment:
Provision for medical/psychosocial support	Yes [ ] No [ ] Comment:
Provision for treatment for study related injuries:	Yes [ ] No [ ] Comment:
Provision for compensation	Yes [ ] No [ ] Comment:
Statistics to be used:	Appropriate/clear [ ] Not appropriate/clear [ ] Comment:
Plans for dissemination of results	Appropriate/clear [ ] Not appropriate/clear [ ] Comment:

Budget	Justifiable/justified [ ] Not Justifiable/justified [ ] Comment:
Decision	Approved [ ] Approved with recommendations [ ] Resubmit revised version [ ] Disapproved [ ] Comments:
Signature…….	Date …….

APPENDIX 3: FORM HK/IREC 04 - 02 DECISION OF THE REVIEW BY COMMITTEE MEMBERS

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCHETHICS COMMITTEE

APPLICATION SUBMISSION Form HK/IREC 04 - 02

APPENDIX 3

Decision of the Review by Committee Members

Date of Review (D/M/Y): .....Protocol No:.....

Protocol Title:	
Elements Reviewed (HK/IREC 04-01)	☐ **Attached** ☐ **Not attached**
Review of Revised Application ☐ **Yes** ☐ **No**	**Date of previous review:**
Decision of the IREC: ☐ **Approved** ☐ **Approved with recommendation** ☐ **Resubmission** ☐ **Disapproved**	**Comments:**

No:	**Participating IREC members/reviewers (Name and Signature)**	**Decision**			
	Signature	**AP**	**AR**	**RES**	**DA**
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					

Note: AP – Approved; AR – Approved with recommendation; RES – Resubmission for re-review; DA – Disapproved

Chairperson: .....Signature:.....Date: .....

APPENDIX 4 FORM HK/IREC 04 - 03: SUMMARY OF DECISION OF REVIEW BY CONSULTANT(S)

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

APPLICATION SUBMISSION

SUMMARY OF DECISION OF REVIEW BY CONSULTANT(S)

FORM HK/IREC 04 - 03
APPENDIX 4

Protocol title ---------- Protocol No: ----------

	New Protocol	Resubmission	Protocol amendment
Date of review			
Elements reviewed:	Attached [ ] Not attached [ ]	Attached [ ] Not attached [ ]	Attached [ ] Not attached [ ]
Decision of and comments of Consultant 1	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments
Decision of and comments of Consultant 2	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments

Decision of and comments of Consultant 3	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments	Approved [ ] Approved with recommendations [ ] Resubmission [ ] Disapproved [ ] Comments

APPENDIX 5 FORM HK/IREC 05: PROTOCOL AMMENDMENT FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 05
APPENDIX 5

PROTOCOL AMMENDMENT FORM

Protocol title:
Protocol No:
IREC Medical Advisor:
Type of amendment requested: Expedited [ ] Full review [ ]

Signatures: ---------- Date ----------
Principal investigator

---------- Date ----------
Medical Advisor

---------- Date ----------
Medical/Scientific Director

Approvals ---------- Date ----------
Chairperson, IREC

---------- Date ----------
Secretary, IREC

APPENDIX 6 FORM HK/IREC 07 CONTINUING REVIEW APPLICATION/ASSESSMENT

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 07
APPENDIX 6
CONTINUING REVIEW APPLICATION/ASSESSMENT

<table>
<tr><td colspan="3">Protocol title:</td></tr>
<tr><td>Protocol No:</td><td colspan="2"></td></tr>
<tr><td>Medical advisor:</td><td colspan="2"></td></tr>
<tr><td>Action requested:</td><td colspan="2">Review for new subject accrual to continue [ ]
Review for enrolled participants follow-up only [ ]
Review for termination of study [ ]</td></tr>
<tr><td rowspan="2">Have there been any amendments since last review?</td><td>Yes [ ]</td><td>Comment</td></tr>
<tr><td>No [ ]</td><td>Comment</td></tr>
<tr><td>Accrual exclusions</td><td colspan="2">None [ ] Male [ ] Female [ ]
Others (Specify)</td></tr>
<tr><td>Impaired participants</td><td colspan="2">None [ ] Physical [ ] Mentally [ ] Both [ ]
Others (Specify)</td></tr>
<tr><td>Have there been any changes in the participant population, recruitment or selection criteria since the last review?</td><td colspan="2">No [ ] Yes [ ] Explain</td></tr>
<tr><td>Have there been any changes in the informed consent process or documentation since the last review?</td><td colspan="2">No [ ] Yes [ ] Explain</td></tr>
<tr><td rowspan="2">Has any information appeared in the literature or evolved from this or similar research that might affect the Committee’s evaluation of the risk/benefit analysis of human subjects involved in this protocol?</td><td>Yes [ ]</td><td>Comment</td></tr>
<tr><td>No [ ]</td><td>Comment</td></tr>
<tr><td>Have any participants</td><td colspan="2">No [ ] Yes [ ] Explain</td></tr>
</table>

withdrawn for this study since the last approval?	
Summary of protocol participants	Accrual ceiling set by the IREC: [ ] New participants accrued since last review [ ] Total participants accrued since protocol began [ ]

Have any unexpected complications or side effects been noted since last review?	Yes [ ]	Comment
	No [ ]	Comment
Investigational new drug/device	None [ ] IND [ ] IDE [ ] FDC No: [ ] Name:…….. Sponsor: …….. Holder: ……	
Ionizing radiation use (X-ray, radioisotopes, etc)	None [ ] Medically indicated only [ ]	
Have any collaborating sites (institutions) been added or deleted since the last review?	No [ ] Yes [ ] (Identify all changes and explanation of changes)	
Changes in medical advisory/investigation?	None [ ] Deleted ---------- Added ----------	
Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?	No [ ] Yes [ ] (Append a statement of disclosure)	

Signature	Protocol Chairman ……. Date……. IREC Medical Advisor …….. Date ……... Scientific Director ……. Date ……...
Committee Comment/decision	

Approval	Chairperson, IREC …….. Date …….
Completion	Secretary, IREC …….. Date …….

APPENDIX 7 FORM HK/IREC 08: CONFIDENTIALITY / CONFLICT OF INTEREST AGREEMENT

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

FORM HK/IREC 08
APPENDIX 7

CONFIDENTIALITY / CONFLICT OF INTEREST AGREEMENT

In recognition of the fact, **(IREC member's name),** and his/her affiliation herein after referred to as the "Undersigned" and as a member of the HKMU IREC has been appointed to assess health research studies and clinical trials involving human subjects in order to ensure that the studies/clinical trials are conducted in a humane, ethical, and responsible manner with the highest standard of care according to applied international and national codes, guidelines, and regulations.

You have been appointed to become a member of the HKMU IREC as an individual, not as an advocate or representative of your home town/territory/community, nor as a delegate of any organization or private interest. Your fundamental duty is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations based on the merits of the submissions you review.

The HKMU- IREC must meet the highest ethical standards in order to merit the trust and confidence of the communities and the public it is meant to protect. As a member of the HKMU IREC, therefore, you are expected to meet the same standards of ethical behaviour as you carry out your mandate.

This agreement encompasses any information deemed confidential or proprietary given or disclosed to the Undersigned in connection with his/her duties as a member of the HKMU-IREC . Any written information given to the Undersigned which is of a confidential, proprietary, or privileged nature shall be identified and marked accordingly. As such, the Undersigned agrees to hold all confidential or proprietary trade secrets or information in trust or confidence; and agrees that it shall be used only for intended purposes and not for any other business or be disclosed to a third party. Written confidential information given for review shall not be copied or retained. All confidential information, and any copies and notes thereof, shall remain the sole property of the Institutional Research Ethics committee (IREC)

The Undersigned agrees not to disclose or utilize, directly, any confidential or proprietary information belonging to a third party as a fulfilment of this agreement. Furthermore, the

Undersigned confirms that his/her performance of this agreement is consistent with the HKMU policies and any contractual obligations they may have to third parties.

Conflict of Interest:

It is recognized that the potential for conflict of interest shall always exist, but the HKMU has so much faith and trust in the IREC and its Chairperson that they shall manage the conflict issues in such a way that the ultimate outcome shall be the protection of human subjects.

It shall be the policy of the IREC that no member may participate in the review or approval of an activity in which that member has a conflict of interest except to provide information as requested by the Institutional Research Ethics Committee.

You shall immediately disclose to the Chairperson of the IREC any actual or potential conflict of interest that you may have in relation to any particular proposal submitted for review by the Committee, and you shall abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IREC member has a potential conflict of interest, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence which substantiates the claim that a conflict of interest exists with the IREC member(s) in question. The Committee may elect to investigate the applicant's claim of potential conflict.

Whenever a member has a conflict of interest, he/she should notify the Chairperson in writing and may not participate in the IREC's review process or approval except to provide information if the Committee so requests. Conflict of interest situations include:

- A member being involved in potentially competing research programmes.
- Access to funding or intellectual information that may provide an unfair competitive advantage.
- A member's personal biases that may interfere with his or her impartial judgement.

Members who may have a conflict of interest will not be counted in the quorum and may not vote.

Confidentiality and non-disclosure:

In the course of your activities as a member of the IREC, you may be given confidential information or documentation which is hereby referred to as "Confidential Information". You agree to take reasonable measures to protect Confidential Information; subject to applicable legislation, including the Access to Information Act. You shall not disclose Confidential Information to any person, or use Confidential Information for any purpose outside the Committee's mandate and particularly in a manner which would result in a benefit to yourself or any third party. You shall return all Confidential Information, including any minutes or notes you

have made as part of your Committee duties, to the Chairperson upon termination of your functions as a Committee member.

Please sign and date this agreement, if you agree with the terms and conditions set fourth above. This form shall be kept on file in the custody of the Compliance Office, a copy shall be provided for your records

I (name)……..

Address……
……..
Have read and accepted the aforementioned terms and conditions as stipulated in this agreement.

_____ _____
Undersigned Signature Date

_____ _____
Compliance Officer Date

APPENDIX 8 FORM HK/IREC 09A: INVENTORY LOG OF COPIED DOCUMENTS

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 09A
APPENDIX 8

INVENTORY LOG OF COPIED DOCUMENTS

No:	Name SOPs /Guidelines copied	Code No:	Date copied	Number of copies	Number Remaining

APPENDIX 9 FORM HK/IREC 09B LOG OF REQUESTED COMMITTEE DOCUMENTS

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 09B
APPENDIX 9

APPROVAL COVER PAGE

No:	Document	Requested by	Date requested	Retrieved by	Archived by	Date of return

APPENDIX 10 FORM HK/IREC 09C: LOG OF REQUESTED COPIES OF IREC DOCUMENTS

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 09C
APPENDIX 10
LOG OF REQUESTED COPIES OF IREC DOCUMENTS

No:	Document title	Number of copies	Name of recipient and address	Signature of recipient	Initial of the IREC Secretary	Date taken

APPENDIX 11 FORM HK/IREC 11: STUDY REPORT FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 11
APPENDIX 11

STUDY REPORT FORM

Protocol title:	
Protocol No:	
Principal investigator (PI)	
Address	
Telephone No:	
E-mail address:	
Sponsor name:	
Address of sponsor	
Telephone No:	
E-mail address:	
Study site(s)	
Total number of participants:	
Number of participants received the tested articles	
Study articles	
Dosage form	
Study dose(s)	
Duration of the study	
Objectives of the study	1 2 3 4 5
Results so far:	

Name of PI	Signature…… Date……

APPENDIX 12 FORM HK/IREC 12: NON-COMPLIANCE LIST

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 12
APPENDIX 12

NON-COMPLIANCE LIST

No:	Investigator's name/Institute	Non-compliance issue	Decision of the Committee	Date

APPENDIX 13 FORM HK/IREC 13: REQUEST RECORD FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 13
APPENDIX 13

REQUEST RECORD FORM

Date received:	
Received by:	
Requested from:	Telephone No::
	Fax No:----------of ---------- (Date)
	Mailed letter Ref. No:----------of ----------(Date)
	E-mail of ---------- ---------- (Date)
	Hand delivered on ----------(Date)
	Other methods (specify)
Name of Participant:	
Address:	
Title of protocol participated in:	
Starting date of participation:	
Nature and details of request:	
Action taken:	
Outcome:	

Signature: ……..Date: ……

APPENDIX 14 FORM HK/IREC14: CHECKLIST FOR A MONITORING VISIT

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 14
APPENDIX 14

CHECKLIST FOR A MONITORING VISIT

Protocol code:	Date of visit:
Study title:	
Principal investigator:	Phone:
Institute:	Address:
Sponsor:	Address:
Total number of expected study participants:	Total number enrolled:
Any adverse events noticed? Yes [ ] No [ ]	Comments
Any protocol non-compliance/violation? Yes [ ] No [ ]	Comments
Are all case record forms up to date? Yes [ ] No [ ]	Comments
How well are study participants protected? Good [ ] Fair [ ] Not good [ ]	Comments
Any outstanding tasks or results of visit? Yes [ ] No [ ]	Comments
Duration of visit: …… hours/days?	Starting from…… Finished ……..
Name of visiting Committee member/representative:	
Name of companion:	
Completed by:	Date:

APPENDIX 15 FORM HK/IREC15: TERMINATION MEMORANDUM

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 15

APPENDIX 15

TERMINATION MEMORANDUM

Protocol title:			
Protocol No:			
Principal investigator:			
IREC approval date:		Date of last report:	
Starting date:		Termination date:	
Number of study participants		Number of participants enrolled:	
Summary of results:			
Accrual data:			
Applicant name:			
Date of application:			

APPENDIX 16 FORM HK/IREC16: CHECKLIST OF AUDIT AND INSPECTION

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Form HK/IREC 16
APPENDIX 16

CHECKLIST OF AUDIT AND INSPECTION

Internal Audit [ ]	External Audit [ ]	Inspection	Date:
Date(s) for which the audit/inspection has been agreed:			
Shall an interpreter be required? If yes, what arrangement has been made?		Yes [ ]	No [ ]
Review the SOPs and note detail of any omissions or deviations, with reasons			

Check the files for the presence of all signed documents: Note any that is/are missing and action taken.

Components	**Present**	**Missing**	**Action taken**
Background and training records of Committee member	[ ]	[ ]	
Application Submission Records	[ ]	[ ]	
Protocol Assessment Records	[ ]	[ ]	
Communication Records	[ ]	[ ]	
Amendment Approval	[ ]	[ ]	
Meeting Agenda, Minutes, Action letters	[ ]	[ ]	
Active files	[ ]	[ ]	
Continuing and Final reports	[ ]	[ ]	
Are any documents known to be missing from the study master file?			Yes [ ] No [ ]
Which personnel and members shall be available? Give details of times and dates			
What arrangements are there in the event the auditor/inspector needs to make copies of documents?			
Checklist completed by:……			Date: ……..

APPENDIX 17: FORM HK/17A: LOG OF HKMU IREC GUIDELINES' RECIPIENTS

HUBERT KAIRUKI MEMORIAL UNIVERSITY

ETHICS REVIEW COMMITTEE

Form HK/IREC 17A
APPENDIX 17

LOG OF HKMU IREC GUIDELINES' RECIPIENTS

No:	Name of recipient/institution	Guideline code No:	Number of copies	Signature	Date

APPENDIX 18FORM HK/IREC 17B: DELIVERY OF SOP FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY

INSTITUTIONAL ETHICS REVIEW COMMITTEE

Form HK/IREC17B
APPENDIX 18

DELIVERY OF SOP FORM

Date of delivery:	
Name of recipient:	
Address:	
Means of delivery:	
Expenses:	

No:	Items delivered	Codes of items	Number of copies	Remarks

Receiving condition:	Complete items [ ] Good [ ] Poor [ ] Incomplete (specify)
Received by	
Date received	

APPENDIX 19: FORM HK/IREC 17C: DELIVERY FORM OF GUIDELINES

HUBERT KAIRUKI MEMORIAL UNIVERSITY

ETHICS REVIEW COMMITTEE

Form HK/IREC 17C
APPENDIX 19

DELIVERY FORM OF GUIDELINES

Date of delivery:	
Name of recipient:	
Address:	
Means of delivery:	
Expenses:	

No:	Items delivered	Codes of items	Number of copies	Remarks

Receiving condition:	Complete items [ ] Good [ ] Poor [ ] Incomplete (specify)
Received by	
Date received	

APPENDIX 20 FORM HK/IREC 17D: APPROVAL COVER PAGE

HUBERT KAIRUKI MEMORIAL UNIVERSITY
INSTITUTIONAL ETHICS REVIEW COMMITTEE (IREC)

Form HK/IREC 17D
APPENDIX 20

APPROVAL COVER PAGE

	Version 1	Version 2	Version 3
Page(s) for which revision is required/made			
What is revised			
Reasons for revision			

Prepared by			
Position			
Date			

Reviewed by			
Position			
Date			

Approved by			
Position			
Date			

Distribution of the SOP

APPENDIX 21 FORM HK/IREC 18: DOCUMENT REQUEST FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY
INSTITUTIONAL ETHICS REVIEW COMMITTEE

Form HK/IREC 18
APPENDIX 21

DOCUMENT REQUEST FORM

Name of document:		Code:
Requested by:		Date:
Chairperson [ ] Secretary [ ] Committee member [ ]		
Administrative staff [ ] Authority [ ] Others (specify)		
Purpose of request:		
Retrieved by:		Date:……
Returned by:		Date:……
Archived by:		Date:……
Approved by:		Date:……

APPENDIX 22 FORM HK/IREC 19 IREC QUARTERLY REPORT FORM

HUBERT KAIRUKI MEMORIAL UNIVERSITY
INSTITUTIONAL ETHICS REVIEW COMMITTEE

FORM HK/IREC/19
APPENDIX 22

INSITITUTINAL RESEARCH ETHICS COMMITTEE QUARTERLY REPORT FORM

Name of the Institutional Research Ethics Committee
_____

Date of submission_____/_____/_____
DD MM YYY
Period: [] Q1 (Jan-Mar) [] Q2 (Apr-Jun) [] Q3 (Jul-Sep) [] Q4 (Oct-Dec)

S/N	Title of Proposal	IREC approval number	Date approval issued	Source of Fund	Principal Investigator	Contact Information	Type of Study	Duration of study	Study area
1.									
2.									

3.									
4.									
5.									

Comments