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ADMINISTRATIVE STANDARD OPERATING PROCEDURE	Version No: V4-Feb 2023
NAME OF REVIEWER	**DESIGNATION**
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ABBREVIATIONS AND ACCRONYMS

AI	Artificial Intelligence
AKDN	Aga Khan Development Network
AKU	Aga Khan University
CITI	Collaborative Institutional Training Initiative
DRC	Departmental Research/Review Committee
DSMB	Data Safety Management Board
DTA	Data Transfer Agreement
ERB	Ethics Review Board
FHS	Faculty of Health Sciences
GoK	Government of Kenya
GSO	Grants Support Office
HIPAA	Health Insurance Portability and Accountability Act
HPSC	Hospital Patient Safety Committee
IERC	Institutional Ethics Review Committee
ICF	Informed Consent Form
ISERC	Institutional Scientific Ethics Review Committee
MTA	Materials Transfer Agreement
NACOSTI	National Commission for Science Technology and Innovation
PI	Principal Investigator
SAE	Serious Adverse Events
SoP	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
SRC	Scientific Review Committee
ToR	Terms of Reference
URC	University Research Council

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KEY DEFINITIONS

Attendance is defined as the full committee meetings convened with written notice and attract attendance of the ISERC quorum. All ISERC actions will be reflected in the ISERC minutes. Meeting minutes will be reviewed and approved at the next convened ISERC meeting.

Sponsor is referred to as the funding agency for e.g. (URC, Seed Money or External funding agency)

Scholarship is defined as the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines, in the forms of dictionaries, scholarly editions, catalogues and contributions to major research databases.

Proposals evaluated by the ISERC will have the following verdict:

- Approved as per written submission
- Approval of a Protocol with minor corrections
- Approval of a Protocol with major corrections (deferred)
- Disapproval of a Protocol

Approval of a Protocol (approved as written). The protocol is approved as submitted with no changes. Approval will be for a period of one year for all protocols.

Approval of a Protocol with minor Corrections. The protocol is approved pending receipt and review of additional information, which can include minor clarification or modification of the checklist, protocol, consent form, or supporting materials. To qualify for this category, the requested changes must be clearly delineated and not require substantial changes to the protocol or consent form. Written notification of required modifications will be sent to the investigator. The investigator must provide a point-by-point response to all the issues raised by the committee. If a consent form is modified, the new consent form must be attached. The responses and requested modified documents will be reviewed by the Chair, Vice Chair or another ISERC member or designee, on behalf of the ISERC and, if appropriate, the approval will become effective.

Approval of a Protocol with major corrections (deferred) A protocol is deferred when the changes proposed, or questions raised by the ISERC are significant enough to warrant re-review

of the protocol at a subsequent ISERC meeting. The investigator will receive notification of the issues the ISERC needs addressed or changed. If a protocol is deferred it means that it will be reconsidered by the ISERC. In addition to deferring the protocol, the ISERC may ask for additional review by expert consultants outside of the ISERC or an independent duly designate ISERC e.g., appointed by the AKU ERB. An appeal NACOSTI and/or the responsible Minister of Government of Kenya may be also advised.

Disapproval of a Protocol - If the protocol is judged to be lacking in merit, if it compromises the *principles of respect of persons, beneficence and justice*, if it raises ethical questions that cannot be resolved, or if it is decided that the risks outweigh the benefits to the subjects, the protocol will be considered unacceptable and disapproved. The investigator will be notified in writing by the ISERC including the reason(s) for the disapproval and give the investigator an opportunity to respond in person or in writing. The investigator may rewrite and submit the study as a new protocol.

Protocol Deviation occurs when the activities during a study diverge from the ISERC - approved protocol, a variance from protocol. It is an accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the subject, researcher, or research staff. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of a researcher. Examples of a deviation may include a rescheduled study visit, failure to collect an ancillary self-report questionnaire, a subject's refusal to complete scheduled research activities.

Protocol Violation occurs when there is divergence from the ISERC-approved protocol (a deviation) that also reduces the quality or completeness of the data, impacts a subject's safety, rights or welfare and affects the scientific integrity. Accidental or unintentional change to, or non-compliance with the ISERC approved protocol without prior sponsor and ISERC approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data.

Examples of protocol violations will include the following but not limited to the following:

- Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form)

- Loss of laptop computer that contained identifiable, private information about subjects
- Accidental distribution of incorrect study medication or dose
- Not following inclusion/exclusion criteria or Enrollment of subjects not meeting the inclusion /exclusion criteria
- Initiation of study procedure prior to completion of informed consent
- Unreported SAE's
- Improper breaking of the blinding of the study
- Use of prohibited medication
- Incorrect or missing tests (patients' results)
- Mishandled samples
- Multiple visits missed or outside permissible windows
- Inadequate record-keeping
- Intentional deviation from the protocol, good clinical practice or regulations by study personnel in a non-emergency setting
- Repeated noncompliance by the subject
- Repeated deviations of the same nature
- Falsification

Research Misconduct is a fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. Fabrication in this context is defined as making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Noncompliance is defined as any action or activity associated with the conduct or oversight of research involving human participants that fails to comply with research regulations, or institutional policies governing human participants research or the requirements or determinations of the ISERC

Informed Consent is the intent is that **human participants can enter research freely voluntarily)** with full information about what it means for them to take part, and that they give

consent before they enter the research. It includes the **decision capacity**, **documentation of consent, disclosure, and competency**. Documentation of consent is usually evidence by an informed consent form.

Informed consent form will include:

- Description of the research and the role of the participant, including an explanation of all procedures relevant to the participant
- Description of reasonably foreseeable risks
- Description of expected benefits
- Alternatives to participation, such as other studies or services in the area
- Explanation of confidentiality
- Explanation of compensation for injuries or health problems resulting from participation in the study
- Whom to contact about the research if the participant has questions or concerns
- Explanation that participation is voluntary

Complaint refers to an expression of dissatisfaction by a researcher regarding the administration of the functions of the ISERC. It does not include the process of evaluation of the protocol

Conflict of Interest refers to a set of circumstances or conditions in which professional judgment of a primary interest such as the integrity and quality of research tends to be unduly influenced by a secondary interest such as personal financial gain.

Serious Adverse Events is any untoward medical occurrence that occurs after an intervention and may Results in death, is life threatening, subjects the participants to inpatient hospitalization or prolongs their stay in hospital, leads to disability in the study participants or incapacity, causes congenital anomaly/birth defect or jeopardizes the health of the subjects such that they will require medical and/or surgical intervention to prevent any of the above outcomes

SUSAR is a Suspected Unexpected Serious Adverse Reaction is untoward and unintended response that may result due to administration of a drug or study procedure to a study participant in a clinical trial.

Artificial Intelligence (AI) is the use of technology to simulate human intelligence process such as speech recognition, decision making, visual perception using computer systems or machines with the aim of improving human behavior

Algorithmic bias describes systematic and repeatable errors in a computer system that create unfair outcomes, such as privileging one arbitrary group of users over others.

Machine Learning is a branch of artificial intelligence that allows computer systems to learn directly from examples, data, and experience without being pre-programmed

2. POLICY

2.1. Aim and purpose of the SoPs

2.1.1. This Standard Operating Procedures (SOP) set out the requirements for ethics review and approval at the AKU- ISERC in Kenya. These procedures form part of a set of policies designed to guide researchers to ensure proper conduct and integrity of all research undertaken across the AKU, notwithstanding the geographic origins or ontological orientations of such research.

2.1.2. This SOP should be read in conjunction with AKU – Kenya research policies found at https://www.aku.edu/research/policies/Pages/home.aspx; which includes (but are not limited to):

- Policy on Research Ethics Review
- Authorship Policy
- Intellectual Property Rights Policy
- Publications Policy
- Policy on research Misconduct
- Code of Good Research Practice
- Policy on Mechanism for Change of Principal Investigator
- Extramural Grant Application Policy (Pre-award)
- Policy and Guidelines for Intramural Funding

2.2. Ethical Requirements of Human Research

In addition to the principles of responsible research (policies listed in section 2.1.2), the ISERC will base its review of the submitted proposals on the following six ethical criteria.

2.2.1. Social or scientific value

All research involving human participants should provide generalizable results and be socially/scientifically valuable in that it should:

2.2.1.1. Evaluate diagnostic/therapeutic interventions

2.2.1.2. Lead to improvements in health and well being

2.2.1.3. Test hypothesis that should generate important knowledge

2.2.1.4. Disseminate of human research results/findings of the research

2.2.2. Scientific validity

2.2.2.1. Methods must be valid

2.2.2.2. Clear scientific objective/s

2.2.2.3. Use of accepted principles/reliable practices

2.2.2.4. Have sufficient power to test the objective (no biased sample)

2.2.2.5. Offer plausible data analysis plan

2.2.2.6. Proposed plan must be executable/feasible

2.2.3. Fair subject selection

2.2.3.1. Selection of subjects must be fair

2.2.3.2. Inclusion/exclusion criteria of who are/and who are not to be in the study

2.2.3.3. Clear strategies of recruitment must be adopted

2.2.3.4. Fair subject selection requirements

2.2.4. Favorable Risk-Benefit ratio

2.2.4.1. Clinical research involves drugs/devices/procedures where we have limited knowledge and action of the treatment. Thus research entails uncertainty about degree of risk/benefits. Three conditions must be met for research study to be justifiable:

- Potential risks to individuals are minimized
- Potential benefits to individual subjects are enhanced
- Potential benefits to community/society are proportionate or outweigh the risks

2.2.5. Informed consent (I/C) and/or assent

2.2.5.1. Purpose of informed consent is to ensure that individuals enroll and participate in clinical research only when the research is consistent with their values, interests, and preferences

2.2.5.2. To provide Informed Consent, individuals must be accurately informed of the:

- Purpose, methods, risks/benefits and alternative to the research
- Understand this information and its bearing on their clinical situation
- Make a decision that is voluntary and not coerced whether to participate

2.2.5.3. These elements ensure that individuals make rational/free determinations for participation if research is in their interest. I/C embodies the need for respect of persons and their autonomous decisions.

2.2.6. Respect for potential and enrolled subjects

2.2.6.1. Respect for study participants is justified by several principles

- Beneficence (prevent, remove evil/harm and promote good)
- Non-maleficence (do not inflict harm/evil)
- Respect for persons

2.2.6.2. Protecting confidentiality and monitoring wellbeing are motivated by

- Respect for persons
- Beneficence
- Non-maleficence

2.2.7. Universality of the requirements

The above 6 requirements for ethical conduct of health research are universal. They are justified by ethical values that are recognized and accepted in accordance with how reasonable people would like to be treated. The requirements can be amended e.g. in societies where consent of elders is needed before individual consent is solicited. It should be noted that research that is acceptable in one society because its risks outweigh the benefits may have favorable Risk-Benefit ratio in another society. Thus the requirements can be adaptable to situations, cultures, etc.

2.3. Mandate and Scope of Responsibility

2.3.1. The mandate of the AKU Kenya ISERC is to protect the mental, social, physical, welfare, rights, dignity and safety of human participants of research. Research proposals involving humans, whether as individuals or communities,

including the use of fetal material, embryos and tissues from the recently dead, shall be reviewed by the AKU Kenya ISERC. This will be limited to research that involves patients, clients or staff of entities that constitute the agencies of AKDN in Kenya.

2.3.2. These procedures do not prohibit the University from accepting an ethical approval undertaken by another human research ethics committee. However, such an approval will not be sufficient unless endorsed by the ISERC.

2.3.3. The ISERC definition of research is adopted from the UK National Patient Safety Agency Classification of Research, Clinical Audit, and Service Evaluation - Appendix 1: UK National Patient Safety Agency Classification of Research, Clinical Audit, and Service Evaluation. Research is to be understood as an original investigation undertaken in order to gain knowledge and understanding. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship[1]; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products, and processes, including design and construction. It excludes routine testing and routine analysis of materials, components, and processes such as for maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research. ISERC will adopt the UK National Patient Safety Agency classification of research, clinical audit and service evaluation to further define the Committee's area of operation in human research – Appendix 1: UK National Patient Safety Agency Classification of Research, Clinical Audit, and Service Evaluation.

2.4. Objectives

2.4.1. The objectives of the ISERC are to:

2.4.1.1. Protect human subjects in research

2.4.1.2. Promote ethical standards of human research.

2.4.1.3. Review research in accordance with current core values of National Commission for Science, Technology and Innovation (NACOSTI)

2.5. Functions

2.5.1. The ISERC functions are to:

2.5.2. Provide independent, competent and timely review of human research projects in respect of their ethical acceptability.

2.5.3. Facilitate ethical research through efficient and effective review process

2.5.4. Provide ethical oversight, monitoring and advice for approved human research projects.

2.2.5. Prescribe the principles and procedures to govern human research projects including handling of human biological materials and research data.

2.6. Status of the Kenya ISERC within AKU

2.6.1 The AKU in Kenya is one of the teaching sites, an international university within the Aga Khan Development Network (AKDN). The AKDN is a group of private, non- denominational development agencies and institutions working together to improve living conditions and opportunities in over 30 of the poorest countries in the developing world. Research at AKU is centrally governed by University Research Council (URC) which carries forward and supports the research mission of AKU.

2.6.2. To ensure rigor, efficiency and relevance to the geographical and disciplinary context, the AKU has adopted a two-tiered system. This comprises of an AKU wide Ethics Review Board (ERB) responsible for policy-making, governance, and oversight of the ethics review process across AKU and for hearing of appeals. The ERB reports to the University Research Council (URC) and submits annual report to the URC.

2.6.3. The ISERC in Nairobi, Kenya is one of the AKU ERCs and reports administratively to the ERB through its chair.

2.6.4. The ISERC is responsible for (a) granting ethical approval (b) suspending ethical approval and (c) withdrawing ethical approval for research to be carried out within the institutions noted in 2.3.1.

2.7. Accountability

2.7.1. The AKU ISERC is accountable to the AKU ERB in administrative matters only and to NACOSTI in ethics review.

2.7.2. The ISERC shall provide an annual report to the ERB at the end of each calendar year, which shall include information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcome, and general issues raised.

2.7.3. The ISERC may from time to time bring to the attention of the ERB issues of significant concern.

2.7.4. The ISERC shall provide an annual report to NACOSTI as per the templates provided by NACOSTI

3. COMPOSITION

3.1. Membership

The Kenya ISERC composition is adopted from the NACOSTI guidelines for accreditation of ethics review committees in Kenya (Version March 2017). The membership of the ISERC shall include:

3.1.1. at least seven members and if more, the total membership must be an odd number

3.1.2. a chairperson who must have some basic training and/or experience in research ethics and leadership

3.1.3. a vice-chair who will be elected from among its members once the committee is formed

3.1.4. At least one member shall be a lay person. *Lay member* means a member of an ISERC who is not:

- Currently, or has recently been, a registered health practitioner or researcher (for example, a doctor, nurse, midwife, dentist or pharmacist);
- An officer of, or someone otherwise employed by, any health board, health authority, the ministry of Health or medical school;
- Involved in conducting health research or employed by a health research agency or a sector that undertakes health research; or
- Construed by virtue of their employment, profession or relationship, to have a potential conflict of interest or professional bias in a majority of research proposals reviewed.

3.1.5. At least two members shall have research expertise and experience

3.1.6. A member with knowledge of, and current experience in, the professional

care, counselling or treatment of humans

3.1.7. At least one member who is a minister of religion, or a person who performs a similar role in the community;

3.1.8. At least one member who possesses knowledge and understanding of the Kenyan Law

3.1.9. At least one third of the members of the committee shall be of either gender

3.1.10. At least one of the members shall be from outside the institution

3.1.11. The Committee may invite attendance of other members from time to time on need-arise basis to advise on certain technical aspects as may be necessary

3.1.12. To ensure that the ISERC is equipped to address all the relevant considerations arising from the different categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.

3.2. Quorum

For the purposes of holding a meeting of the ISERC, a quorum shall exist when

3.2.1. A representative of each of the categories designated in section 3.1 is present. In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. Attendance of meetings will be virtual or physical and will be communicated prior to the meeting.

3.2.2. However, in those circumstances (3.2.1), there must be at least 50% of the members present to achieve quorum, including one of each of the following categories: Chair/Vice Chairperson, lay person and researcher familiar with the types of proposals that are under review in the ISERC meeting.

3.2.3. The ISERC shall be free to consult any person(s) considered by the ISERC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.

3.3. Appointment

3.3.1. The appointments to the ISERC shall be the responsibility of the Associate Dean - Research with the approval of the Dean of the medical college.

3.3.2. New members of the ISERC shall be identified through one of the following processes

- Reappointment of a current member upon expiry of their initial term of

appointment

- Application for appointment by an individual faculty member
- An open advertisement to the AKU faculty and other local institutions
- Nomination by current member(s) of ISERC

3.3.3. Appointments will be on voluntary basis.

3.3.3. Appointments shall allow for continuity, development of expertise within the ISERC, and the input of fresh ideas and approaches.

3.4. Terms of appointment

3.4.1. Members are appointed for a period of two years and may be reappointed at the discretion of the Associate Dean of Research in Kenya; in consultation with the ISERC chair and with the approval of the Dean of the medical college.

3.4.2. The chair of the ISERC will be appointed by the Associate Dean - Research with the approval of the Dean of the medical college.

3.4.3. The Research Administrative Manager shall be the secretary to the ISERC with no voting power.

3.4.4. The Associate Dean of Research in Kenya may terminate a member's tenure due to:

- Failure to attend three consecutive meetings of the ISERC without reasonable excuse or without notifying the Chairperson, unless exceptional circumstances exist.
- Abuse of office.
- Non-disclosure of competing interests.
- Inappropriate behavior e.g. leering
- Unprofessional conduct.
- Failure to abide by the terms of appointment.

3.4.5. A member may resign from the ISERC at his or her own volition by giving notice in writing to the Chairperson. The chair will provide such notice to the Associate Dean of Research in Kenya. Upon receipt of such notice, steps shall be taken to fill the vacancy of the resigning member.

3.4.6. Members shall be provided with a letter of appointment, which shall include date of appointment, length of tenure, ISERC meeting attendance responsibilities and general responsibilities as an ISERC member.

3.5. Conditions of appointment

3.5.1. Members must agree to their names and professions being made publicly available, including being published on the AKU website.

3.5.2. Members are not offered remuneration. However, external (not employees of AKU) members shall be provided with honorarium in attending ISERC meetings and be reimbursed for legitimate expenses incurred or in otherwise carrying out the business of the ISERC

3.5.3. By accepting the appointment, each member commits to ensure

- that all matters of which he/she becomes aware during the course of his/her work on the ISERC shall be kept confidential;
- Each member accepts that any "conflicts of interest" which exist or may arise during his/her tenure on the ISERC shall be declared;
- Each member accepts that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a ISERC member.

3.6. Education for ISERC members

3.6.1. Newly appointed members shall be provided with adequate orientation on their role as ISERC members of AKU. They will be required to undertake a certificate course on being an ISERC member, CITI training and required NACOSTI training or any other appropriate certification.

3.6.2. Throughout their tenure, members shall be supported to attend conferences and workshops relevant to the work and responsibilities of the ISERC, at the expense of the AKU.

4. CONDUCT OF BUSINESS

4.1. Procedures

4.1.1. The ISERC shall perform its functions according to written standard operating procedures. These procedures shall be reviewed at least every five years and amended and updated as necessary. All ISERC members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to any proposed changes.

4.2. Meetings

4.2.1. The ISERC shall meet on a regular basis, which shall normally be at monthly intervals – subject to workload.

4.2.2. Meeting dates and agenda closing dates shall be circulated and diarized at the beginning of each calendar year.

4.2.3. Any member of the ISERC who has any conflict of interest, financial or otherwise, in a proposal or other related matter(s) considered by the ISERC shall declare such interest prior to its consideration. If the member is present at a meeting at which the matter is considered, the member shall withdraw from the meeting until the ISERC's consideration of the relevant matter has been completed. The member shall not participate in the discussions and shall not be entitled to vote in the decision with respect to the matter. The declaration of interest and absence of the member concerned shall be recorded in the meeting minutes

4.2.4. The ISERC shall endeavor to reach a decision concerning the ethical acceptability of a proposal by consensus. Any significant dissenting view or concern shall be recorded in the minutes. Where a unanimous decision is not reached, the decision shall be considered to be carried by a majority of two -thirds of members who present at the meeting, provided that the majority includes at least a layperson.

4.3. Advocates and interpreters

4.3.1. The ISERC shall consider whether an advocate for any participant or group of participants should be invited to the ISERC meeting to ensure informed decision- making.

4.3.2. Where research involves the participation of persons unfamiliar with the English language, the ISERC shall ensure that the *participant information sheet* is translated into the participant's language comprehension and /or that an interpreter is present during the discussion on the project.

4.4. Attendance of an Observer

4.4.1. An observer or observers may be invited to attend the ISERC meetings, subject to written invitation setting out the terms under which observer status is permitted. These include: signing of a confidentiality agreement, detailing the purpose of the

attendance and the concurrence of the ISERC members on the meeting to be attended by the observer(s).

4.4.2. An observer or observers shall have no vested interest in the scientific or management responsibility for any applications being considered at the ISERC committee meeting.

4.4.3. The Chairperson shall verbally inform any investigator who attends the meeting whenever an observer is present. The investigator shall be given the opportunity to object to or approve the presence of any observer. If there is an objection, the observer shall be requested to leave the meeting room during the discussion of that item of the agenda.

4.4.4. The ISERC meetings, or parts of meetings, may also be attended from time to time by representatives of the AKU Research Committee or Research Office Senior management. The arrangements for such attendance shall be discussed and agreed upon in advance with the ISERC Chairperson and shall be subject to the terms and conditions set forth for the attendance as an observer.

4.4.5. The attendance of an observer or observers shall be recorded in the minutes.

4.5. Ethical review pathways

All Submissions to the ISERC are done online. They will be submitted to the Research office email or to the infonetica Ethics Review Manager using the link https://akunairobi.review.ethicalreviewmanager.com/ or as appropriate. The ISERC will only review protocols emanating from residents, faculty or employees of AKU. External reviews will only be done for studies that intend to study various variables that directly touch on the Aga Khan University in Nairobi, the Aga Khan Development Network and AKUHN staff, patients or its premises. The review will be focused on research protocols involving human participants. The ISERC will not undertake to review other protocols outside this scope.

4.5.1. Full Committee Review

4.5.1.1. The ISERC shall review new applications at its next available meeting providing the complete research proposals or applications are received by the Research Office on or before the closing date i.e. not later than ten working days before the next meeting date. Late submissions will automatically be rolled-over to the subsequent meeting.

4.5.1.2. Based on expertise, ISERC secretary shall then identify two reviewers who will be designated as the primary reviewers of the given application. The primary reviewers must not have either a vested interest in the study (i.e. be named as an investigator or have a supervisory or advisory role) or a conflict of interest (i.e. be involved in the research or in research that competes with the research proposal or application under review or have a financial interest in the sponsor or the outcome of the research).

4.5.1.3. The primary reviewers will evaluate the ethics merit of the proposal and, may also comment on the scientific/methodology aspects of the proposal. The Research Office will then collect written reports from the primary reviewers prior to the committee meeting.

4.5.1.4. During the full Committee review meeting, the primary reviewers will lead the discussion by first presenting an overview of the proposal to the full committee. They will thereafter point out any scientific or ethical issues and facilitate the resolution of any issues raised by committee members.

4.5.1.5. The committee will then make a decision within one of three categories approved, approval with minor or major revision, or disapproval. Applications with minor/major recommendations for revision must be resubmitted for formal approval to be granted.

4.5.1.6. The committee's decision will be based on:

- The scientific validity of the research question.
- The relevance of the proposed study to the health needs of the community under study.
- The risks to potential research participants are minimized and are reasonable in relation to anticipated benefits.
- The safeguards are provided to protect the rights and welfare of vulnerable research participants.
- Whether or not informed consent/assent will be obtained from research participants and adequately documented.
- The need for use of identifiable or potentially identifiable information.
- The level of access to information in relation to achieving the study's objectives.
- The plans for collection, storage and protection of research data and/or biological samples/specimens.
- The provisions for compensation of research participants e.g. for their time,

transport costs or lost wages.

4.5.2. Ratification of approval from another institution/ multicentre research

4.5.2.1. A multicentre research project is defined as a research study proposing to use more than one site/centre for participant recruitment; aiming to include a large number of participants, incorporate different geographic locations thus enhancing the possibility of inclusion of a wider range of population groups, and to compare results among centres, all of which increase the generalizability of the study

4.5.2.2. In the multicentre research projects, each institution is responsible for safeguarding the rights and welfare of human subjects.

4.5.2.3. To facilitate multicentre research the ISERC will:

- Review the protocols with or without the approval of another ISERC in Kenya accredited by NACOSTI
- Accept a scientific/technical and/or ethical assessment of the research by another accredited Kenyan ISERC upon an expedited review to ensure compliance with institutional guidelines.
- Enter into a joint review arrangement, or make similar arrangements for avoiding duplication of effort – subject to the approval of the Associate Dean of Research in Kenya and the National Commission of Science Technology and Innovation.

4.5.3. Expedited review

4.5.3.1. Expedited Review is defined as the review of an application by the ISERC chairperson and by one or more experienced reviewers designated by the chairperson from among members of the ISERC. In reviewing the research, the reviewers may exercise all of the authorities of the ISERC except that the reviewers may not disapprove the research. A research activity may be disapproved only after discussion in a full committee review sitting.

4.5.3.2. The ISERC may use the expedited review procedure to review either or both of the following:

- Certain kinds of research involving no more than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
- Other items of business that are considered to be of minimal risk to participants such as expected adverse events, protocol reports, and minor amendments.

4.5.3.3. The decision of any such meetings shall be tabled for ratification at the next ISERC meeting.

4.5.4. Exemption from review

4.5.4.1. Studies in which human subjects are not involved directly, or no intervention is done shall be exempted from full committee review process. It is necessary that the researchers get an approval normally provided as an exemption letter from ISERC *before* starting the study as it is unacceptable for ISERC to review studies retrospectively. Whilst completing the main application form, a researcher will indicate that the application falls in the exemption category.

4.6. Documentation

For a thorough and complete review, all new submissions should be accompanied with a duly completed application form;

4.6.1. Full Submission

Information captured within the proposal or as attachments in the appendix sections with appropriate referencing in the table of content

- Name of the applicant with designation
- Name of the Institution/ Hospital / Field area where research will be conducted.
- Protocol of the proposed research
- Ethical issues in the study and plans to address these issues.
- All relevant enclosures like proforma, case report forms, questionnaires, follow - up cards
- Informed consent process, including patient information sheet and informed consent form in local language(s).
- For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
- Curriculum vitae of all the investigators with relevant publications in last five years.
- Any regulatory clearances required.
- Source of funding and financial requirements for the project.

- Other financial issues including those related to insurance
- An agreement to report all Serious Adverse Events (SAE) to ISERC
- Statement of "conflicts of interest", if any.
- Agreement to comply with the relevant national and applicable international guidelines.
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ISERCs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
- Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
- Any other information relevant to the study

4.6.2. Submissions, notifications and approvals

4.6.2.1. All applications for ethical approval must be submitted at least ten working days prior to a given meeting date, in writing, in the format approved from time to time by the ISERC and shall include such documentation as the ISERC may specify. Late submissions will be rolled-over to the subsequent meeting.

4.6.2.2. All trainee submissions to ISERC shall be processed through the AKU Scientific Research Committee as appropriate with a confirmation by the respective Departmental Review Committee (DRC) that the proposed work is scientifically sound. Guidelines shall be issued to assist applicants in the preparation of their applications.

4.6.2.3. The ISERC may request the applicant to supply further information in relation to an application and/or request the applicant to attend a meeting of the ISERC at which the application shall be considered for the purpose of providing information to and answering questions from the ISERC members.

4.6.2.4. The ISERC shall consider every correctly completed application, which it receives at its next available meeting following receipt, provided that the application is received before the relevant closing date.

4.6.2.5. The Research Office shall circulate the meeting agenda to members of the ISERC at least three (3) working days prior to the next meeting.

4.6.2.6. The ISERC may consult the Research Committee for scientific/technical matters for clarification as necessary. The ISERC may also obtain expert scientific/technical advice, subject to paragraph 3.2.3 from outside the Research Committee.

4.6.2.7. The ISERC may take into account the opinions or decisions of another human research ethics committee in relation to a research protocol.

4.6.2.8. A decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of ISERC support staff

4.6.2.9. Following its review, the ISERC shall promptly notify the applicant through the Chair in writing, advising whether the application requires modifications in (to secure approval) or has received ethical approval (and any conditions of the approval) or has been disapproved.

4.6.2.10. Where recommendations for modification and, or clarification has been requested, the applicant will be expected to make a resubmission within two months, failure to which the ISERC will remove the application from its agenda and the PI will be expected to reapply.

4.6.2.11. The reviewers will be allowed up to fifteen working days to review resubmissions and provide feedback

4.6.2.12. For resubmissions, the ISERC will advise the PI on documents needed, which will include:

a) A detailed point by point response to each recommendation / comments requested by the Institutional Scientific Ethics Review Committee
b) In-text comments/track-changes in the main proposal i.e. using a different font color, in-text responses alongside the reviewer comments in in the main proposal
c) A final clean copy of the revised proposal (i.e. with no track changes)
d) Any other document as may be determined by the ISERC

4.6.2.13**.** In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. If the ISERC has granted approval, it shall inform the applicant in writing that the research may commence subject to adherence

with laid down guidelines.

4.6. Transfer of Biological Samples

4.6.1. When human biological samples are to be shipped from AKU to another country as part of a research study, there should be justification for such export. The export of biological samples may be justified if there is lack of capacity to analyze the samples locally or in cases of multicenter studies where samples for quality assurance are shipped for analysis in one site. The ISERC may however assess whether any effort is being made to capacitate the "weaker" partner through training/capacity building and equipment supplies, particularly if the research project has possibilities of operating within AKU for more than 2 years in which case it would be recommended that capacity building through transfer of equipment should form part of the funding. Exceptions to this are research projects where the expertise and the requisite equipment may be expensive or scarce and specimens may still have to be exported.

4.6.2. The ISERC will only give ethics approval for a given proposed research study, the permit/permit for exportation of the samples will be referred to the Ministry of Health or relevant national regulatory body for concurrence.

4.6.3. Submissions for ethics review should also include a proposal for biological specimens transfer where specimens will be shipped out of the country and must be accompanied by a Material Transfer Agreement (MTA). MTA templates can be obtained from the Research Office.

4.6.4. In addition to the MTA, application for ISERC review shall include:

- A detailed description of the quantity and type of sample/specimen to be shipped
- Explicitly defined number, type and dimension of tissue blocks to be exported
- Participants consent and/or assent documents which must have specified that the samples/specimens in question would be shipped to a particular destination for the purpose(s) described.
- Length of storage of the samples which should not be beyond the specified period of analysis in the study protocol or beyond the approved study period. If there are plans for long-term storage of the samples overseas, this must be stated in the proposal. The ISERC encourages local long-term storage of samples. Consideration shall however be made for multicentre studies which require that a repository be formed at a coordinating centre outside Kenya. In such cases, the ISERC shall require that a similar repository be held at a local-AKU research facility.

4.6.5. Submissions of the requests to export samples shall be reviewed by a member of the ISERC and tabled in the ISERC Full Committee Meeting. The timelines for submission shall be as per the schedule provided for ISERC full committee meeting every year

4.6.6. The samples/specimens at the overseas coordinating centre should be destroyed within sixty days after completion of the study or as may be advised by the ISERC. A *memorandum of destruction* of the biological samples or specimens must be submitted to the ISERC within three (3) working days of the event. In cases where remaining samples will not be destroyed, they should be shipped back to AKU within sixty days (60) after completion of the study.

4.6.7. It is the responsibility of the researcher to ensure that there are structures at the receiving institution abroad that will take charge of the ethical issue related to the exported samples.

4.6.8. If extended storage of samples (beyond the duration of the approved period of the research study) is anticipated, the researcher must indicate the same in research proposal specifying the exact location of sample storage, duration of storage (for a specific period), analysis to be done, and reasons for storage

4.6.9. In the event that further studies (other than those stated in the research protocol) are proposed on the stored or exported samples, the ISERC must be informed and fresh approval of the new studies requested.

4.6.10. After a positive ethics review by the ISERC, a copy of the proposal (stamped and dated), MTA (reviewed by AKU legal Office and endorsed by an Official Signatory of AKU), and ISERC approval letter must be submitted to the Ministry of Health and NACOSTI for purposes of obtaining a Material Transfer Permit.

4.7. Data Transfer

All researchers who seek to share or receive data from and to AKU must be in accordance with the Kenya Data Transfer Act of 2019. Data Importers and collaborators in projects will only use the provided data as intended and may not do further analysis, interpretation and publication without the ethical approval of the ISERC.

Data emanating from patients must be held in high confidentiality and should be coded and devoid of personal identifiers (such as identity numbers, telephone numbers and email addresses). During transmission, data should be transcribed for security and sent in a protected manner to

the data recipient. Such mechanisms of protection must be well stipulated in the Data Transfer Agreement. Submissions to the ISERC for review will take not less than ten days and will be presented to the full committee meeting as per the ISERC calendar.

In addition to the DTA, application for ISERC review shall include a detailed description of:

- The ISERC approved research protocol
- The Source of data that will be transferred
- The reason for data transfer
- Mechanisms through which the data will be exported and imported back.
- Steps that the researcher has put in place to ensure data safety and security during transfer, export and importation of the data.
- Communication with the study participants on the outcomes of their analyzed data (Data dissemination plan)
- Period within which data will be held by the data Importer.

Where approvals have been granted, the ISERC shall issue a supporting letter to allow the researcher export or import data.

4.8 Review of Research involving Machine Learning and Artificial Intelligence

Artificial Intelligence systems are information-processing technologies that integrate models and algorithms that produce a capacity to learn and to perform cognitive tasks leading to outcomes such as prediction and decision-making in material and virtual environments.

4.8.1 Algorithmic Bias and Fairness. Investigators shall make attempts at correcting algorithmic bias in automated decision processes majorly based on Machine learning models to eliminate factors or outcomes that may disadvantage certain groups or individuals during the lifecycle of the AI system. Investigators shall take an inclusive and participatory approach in ensuring that the benefits of AI technologies are understandable, available and accessible to all stakeholders, especially AI systems with locally relevant content and services, and with respect for multilingualism and cultural diversity.

Artificial intelligence (AI)-based systems or techniques, including robotics in research will observe the following during the conduct of research

- **Respect for human society;** human beings must be respected to make their own decisions and carry out their own actions. This includes autonomy**, dignity,** and **freedom**.
- **Privacy, personal data protection and data governance;** people have the right to privacy and data protection, and these should be respected at all times.

- **Fairness:** people should be given equal rights and opportunities and should not be advantaged or disadvantaged undeservedly.
- **Individual, social, and environmental well-being and safety;** AI systems should contribute to, and not harm, individual, social and environmental wellbeing.
- **Transparency:** the purpose, inputs and operations of AI programs should be knowable and understandable to its stakeholders.
- **Accountability and oversight:** humans should be able to understand, supervise and control the design and operation of AI based systems, and the actors involved in their development or operation should take responsibility for the way that these applications function and for the resulting consequences. **AI Bias:** The AI systems adopted will have mechanisms set out to look for potential biases that may exist and put in place mechanisms to solve the biasness. AI biases arise from human bias and systemic/institutional bias. - Put in place mechanisms to ensure that the data systems are not vulnerable to manipulation and deception

During their review, the ISERC shall ensure that protocols under review have the following components

- Researchers will ensure appropriateness in deciding how the algorithm should be used in the local context, and properly matching the machine learning model to the target population.
- Investigators will ensure they mitigate biases and entrench fairness by examining the impact on various demographic groups and choosing the most appropriate group that will adequately satisfy the desired set of scientific outcomes while respecting cultural, social and legal foundation.
- Further, in order to ensure fairness and confidence in the AI research activity, researchers should ensure their databases can be accessed and inspected by the ISERC if need be, in respect to the sources of the data used and generated, as well as how the systems make decisions. Researchers should point out and justify any lack of inspect ability of the data/source/system.
- Investigators should clearly identify the proposed benefits and probable risks of AI algorithm that is being studied, as well as appropriate risk prevention, mitigation and monitoring measures.
- Investigators should clearly stipulate how harms caused through AI algorithm will be investigated, addressed and redressed. Researchers to present a balanced review of their risks and opportunities presented by their development as they are the most

knowledgeable of what their systems can do. This will enable the ISERC to make an informed decision.

- Continued monitoring of the hospital care and management of the Artificial systems to identify any gaps arising as the project is being implemented. Clear description of skills and knowledge required by the users of the AI.

- A multi skilled team to evaluate the performance of the A.I. A multidisciplinary approach will be required in dealing with AI projects. The researcher should ensure the intended and unintended results of the ongoing M&E of the system are addressed.
- The Informed consent form shall clearly explain the role of the AI in the study and shall be evaluated on a case by case basis. The ICF template adopted at AKUH shall be used.
- The Data Transfer and Protection Act of Kenya, 2019 shall abide
- Data collected must be data that is required for the study. Collection of geo-coordinates will be generalized to ensure that only the required coordinates are collected. The coordinates shall be de-identified to protect the research participants, their families and communities.
- In instances where the data collected on A.I systems is able to provide indicative findings, outside the approved objectives, the P.I will be required to re-consent the patients, apply for an amendment of the protocol before such data can be analyzed and disseminated.
- As AI data is commercialized, the P.I will be required to be transparent and provide all the information relating to the study benefits and risks before commercialization. Extreme profitability.
- All P. I's with protocols involving A.I will be required to sign the full disclosure form.
- End-users of artificial intelligence-based systems or techniques should demonstrate autonomy in their research proposals.
- End-users' subordination, coercion, deception, manipulation, objectification or dehumanization should be avoided in research proposals involving AI.
- End users should have some control over the AI systems directly or indirectly (through operators). This should a consideration in research involving A.I.
- Purposeful attachment or addiction of the end user to AI systems should be avoided ensuring continued free personal will. This should a consideration in research involving AI.
- All end-users of AI should be provided with adequate information, education and

communication about the benefits alternatives, and risks of AI use. Researchers should clearly state how this will be achieved in their research proposals.

- All AI systems should be complaint the data protection Law of Kenya. A statement referencing the data protection Laws of Kenya, or any other applicable laws should be referenced in their research proposals.
- Data should be acquired, stored and used in a manner which can be audited by humans. This should be described in the research proposal.
- Research proposals about AI demonstrate that data about potential participants is representative of the target population and reflects diversity or is sufficiently neutral (No bias in selection), this includes any outputs from the AI. Must not unduly or unfairly seek to lower the psychosocial and environmental well-being potential research participants.
- Research proposals about AI should demonstrate universal accessibility and safety, offering equitable functionality and benefits to all end users with different disabilities. The proposal should also describe how well the system can be audited by the ISERC, and other regulatory bodies.
- Research proposals should offer details about how decisions made by the system will be explainable to users and how possible ethical and socially undesirable effects of AI (Bias, lack of transparency, loss of privacy) will be prevented and/or corrected.

4.9 The ISERC requirements for Case reports

A case report is a detailed explanation of the course of medical treatment of a patient that may have resulted in a unique outcome. It details the handling of a unique clinical case which in either case did not have any research intent at the time of the intervention and there was no plan to systematically evaluate the outcome for purposes other than treating the patient. The detail in the report include diagnosis, treatment, and follow-up of an individual patient. Case reports also contain some demographic information about the patient (for example, age, gender, ethnic origin).

A case report attempts to describe the treatment of a single patient and does not meet the definition of human subject's research at AKUHN (HIPAA,1996). Investigators at AKU are required to submit a case report to the ISERC for approval before publishing.

Key ethical considerations in case reports are:

1. The Written Informed Consent Form
2. Ensuring confidentiality

3. Recognizing that anonymity cannot be guaranteed if any personally identifiable information will be collected.

Note a case report involving more than one human subject meets the definition of human subject's research and requires ISERC Full Committee review.

A summary describing the case, the type of information that will be included and the safeguards for protecting confidentiality must be submitted to the ISERC before the abstraction of patient data. The investigator will be required to provide written evidence that the informed consent of the subject was sought prior to publication of the case report. Prior to presentation or publication of a case report, the ISERC will require documentation by the clinician that the confidentiality and privacy of the subject was upheld.

The following listed items (HIPAA identifiers) must be de-identified from the subject

- Names (individual, employer, relatives, etc.)
- Address (street, city, county, zip code – initial three digits if the geographic unit contains less than 20,000 people, or any other geographical codes)
- Telephone/Fax Numbers
- National Identification Number, National Health Insurance Fund Number, National Social Security Fund Number or any other numbers that are officially assigned by the government
- Dates (except for year)
    - Birth Date
    - Admission Date
    - Discharge Date
    - Date of Death
    - Patient ages >89 and all elements of dates indicative of such age (except that such age and elements may be aggregated into a category "Age>90"
- E-mail addresses/URLs (Web Universal Resource Locators)/IP (Internet Protocol) addresses
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate/License Numbers
- Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g. finger or voice prints or full face photographic images)
- Any other unique identifying number, characteristic, or code

Case report de-identification reporting form

1. Name of the Principal Investigator _____
2. Case report title _____
3. Indicate the source of de-identified data _____
4. List the information required in the de-identified data set

   _____
5. Attach a copy of the signed/dated informed consent form made by the research subject
6. Include the statement below

Principal Investigator Certification

I certify that the Protected Health Information (PHI) that will be received or reviewed by research personnel for this case report does not include any of the identifiers listed above.

As the P.I, i certify that i do not have knowledge that any of the remaining information could be used, alone or in combination with other information, to identify an individual who is the subject of the information.

Name of the Principal Investigator / Clinician _____

Signature _____ Date _____

5. POST-APPROVAL RESPONSIBILITIES

This section details the responsibilities of the principal investigator and his team after issuance of the ISERC approval and the roles of the research office and the ISERC after issuance of ethics approval on a research protocol

5.1. Follow-up Procedures

5.1.1. The ISERC shall monitor approved projects for compliance with the ISERC's ethical approval. In doing so, the ISERC may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the ISERC shall require investigators to provide annual progress reports, and a final report at completion of the study.

5.1.2. Progress reporting will be done using the prescribed template provided by the research office

5.1.3. The ISERC shall, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of the ethical approval of the project including:

- Protocol deviation and/violation, if any, should be informed with

adequate justifications.

- The ISERC shall consider a protocol deviation as any failure to adhere to the defined study procedures or treatment plans outlined in the protocol version previously approved by the ISERC.
- The ISERC shall consider a protocol violation as any planned or inadvertent changes that may or may not impact safety of study participants, affect the integrity of study data, and/or affect study participants' willingness to participate in the study previously approved by the ISERC.
- Any amendment to the protocol should be resubmitted for renewed approval. This will also include change and or addition of investigators / sites should be submitted for approval
- Any new information related to the study should be communicated.
- All Serious Adverse Events (SAEs) and the interventions undertaken should be reported as soon as they occur but not later than 48 hours. A report from the Hospital Patient Safety Committee should also be submitted.
- Premature termination of study should be reported with reasons along with summary of the data obtained so far.
- If the project is abandoned for any reason.

5.1.4. The ISERC may adopt any additional appropriate mechanism for monitoring as deemed necessary.

5.1.5 In the event of a SAE or unexpected events, it is the responsibility of the Principal Investigator to inform the appropriate offices including the Hospital Patient Safety Committee, ISERC, DSMB and the sponsor as may be required

5.1.6 The SAE and SUSAR report shall be submitted to the ISERC within 48 hours after occurrence of the SAE and the SUSAR.

5.1.7 The research office will maintain a data base of all reported SAEs and SUSARS.

5.1.8 The ISERC shall review such reports and advice the PI on a mitigation strategy which may include a request for the immediate medical care of the affected participants and families, a duty of care plan for the affected study participants, a detailed monitoring plan for the for ongoing study participants and the provision of alternative forms of care by the study sponsor.

5.1.9 The ISERC will liaise with the Data Safety Management Board for their input on the

report SAE and SUSAR in the study and make a determination. Assessment of the SUSAR may lead to the suspension of study activities while investigations are ongoing, a complete stop of the research study or a continuation of the study with a mitigation strategy in place.

5.2. Records

5.2.1. The Research Office shall prepare and maintain records of the ISERC's activities, including

- Agendas and minutes of all meetings of the ISERC
- Curriculum Vitae (CV) of all members of ISERC
- Record of study protocols with enclosed documents, progress reports, and
  SAEs.
- Record of all existing relevant national and international guidelines on research ethics and laws along with amendments
- Record of all correspondence with members, researchers and other regulatory bodies
- Final report of the approved projects.

5.2.2. The Research Office shall prepare and maintain a record for each application received, and any relevant correspondence including that between the applicant and the ISERC.

5.2.3. Records shall be kept securely and confidentially in accordance with the acceptable data protection requirements.

5.2.4. Records shall be held for sufficient time to allow for future reference. The criteria for length of storage shall be guided by the AKU's quality management procedures but will not be less than 7 years for all approved research protocols and a minimum of 20 years for approved protocols for clinical trials.

5.2.5. The minimum period for retention shall be as per prevailing institutional guidelines on records management.

5.2.6. The ISERC shall maintain a record of all the applications received and reviewed.

6. COMPLAINTS AND REVIEW

This section explains the processes that will be undertaken by an applicant in filing a complaint and the processes that the ISERC follows when a complaint is filed. It also details the AKU administrative process of review and dealing with complaints.

6.1. Complaints concerning the conduct of research projects:

6.1.1. Any complaint concerning the conduct of a research project shall be addressed in writing to the ISERC chairperson. The chairperson shall thereupon investigate the complaint and make a decision thereon and notify the complainant accordingly. If the complainant is dissatisfied with the decision of the chairperson, the complainant may refer the same complaint by way of an appeal to the AKU ERB who shall dispose of the complaint in the manner outlined in section 6.1.2

6.1.2. The AKU-ERB may either determine the appeal of its own motion or constitute an ad hoc appellate panel as provided for in section 6.2.4 to hear and determine the appeal. Such an appeal will not be deemed as the decision of the ISERC but may be presented to the ISERC for discussion, approval or disapproval.

6.2. Appeal against the ISERC's Decisions on the review process:

6.2.1. Any person aggrieved by the decision of the ISERC regarding an application for approval of a study proposal submitted to the ISERC, may request the chairperson in writing to have the decision reviewed again by the ISERC by furnishing to the chairperson cogent grounds in support of such a request.

6.2.2. If the chairperson is satisfied that the grounds advanced warrant a further review of the proposal the Chairperson shall direct the applicant to resubmit the study proposal for further review by the ISERC.

6.2.3. The ISERC shall consider the grounds advanced by the applicant in support of a further review and make a decision thereon. The ISERC may invite the applicant to attend the ISERC meeting at which a further review is to be conducted and afford the applicant an opportunity to be heard.

6.2.4. The ISERC shall consider the resubmitted study proposal, make a decision thereon, and notify the applicant of its decision within 7 days of the date of the decision. The applicant, if aggrieved by such decision may prefer a further appeal in writing to the AKU ERB who shall constitute an ad hoc independent Appellate Panel to hear and determine the appeal.

6.2.5. The ad hoc panel in 6.2.4 above shall comprise three (3) persons competent in ethics

review involving human participants one of whom shall be an expert in the field of the subject of research in question and one who shall be a lay person. The AKU-ERB shall nominate the chairperson of the ad hoc panel from among members of the panel. The ad hoc panel shall adopt the procedure set out in Section 6.2.6 in hearing both the appeals from the complaint process in 6.1.1 and the proposal review process in Section 6.2

6.2.6 The panel after hearing the Applicant may:

- Dismiss the appeal
- Refer back the study proposal to the ISERC for further consideration taking into account the findings of the panel
- Refer the study proposal for external review by an independent ISERC where the panel of the AKU ERB is of the opinion that due process was not followed by the ISERC in reaching its decision appealed against

6.2.7 The Applicant may in lieu be adopting the process of appeal outlined above appeal directly to NACOSTI within one month of the outcome of the decision of the ISERC as provided under Guideline 3.0 in the '*Guidelines for Accreditation of Institutional Ethics Review Committees in Kenya, October 2017'*

6.3. Process of handling research misconduct

In case the ISERC is in knowledge of any reported Research Misconduct, they may advise the Principal Investigator on remedial actions as appropriate upon deliberation in a Full Committee Review meeting. Where the ISERC concludes that such misconduct needs further investigation, the Research Misconduct will be handled administratively by university systems and as stipulated in the Policy on Research Misconduct of 2022. The Associate Dean of Research will be notified by the Chair of the ISERC in writing of the research misconduct.

The Associate Dean will then handle the matter of the research misconduct in consultation with the Chair of the University Research Council and notify the ISERC of its verdict upon successful closure or as may be necessary.

7. REVIEW/AMENDMENT OF TERMS OF REFERENCE

7.1. The ISERC shall review the SoPs every five years and propose changes for approval, if appropriate.

7.2. Members of the ISERC may from time to time propose changes to the SoPs for review

by the ISERC. If considered acceptable, such changes shall be signed off by the members and forwarded to the Associate Dean Research for approval if appropriate.

APPENDICES

Appendix i: UK National Patient Safety Agency Classification of Research, Clinical Audit, and Service Evaluation

INSTITUTIONAL SCIENTIFIC ETHICS REVIEW COMMITTEE (ISERC) THE AGA KHAN UNIVERSITY - KENYA

UK National Patient Safety Agency Classification of Research, Clinical Audit, and Service Evaluation

Research	Clinical audit	Service evaluation
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies, explores themes following established methodology.	Designed to answer the question: "Does this service reach a predetermined standard?"	Designed to answer the question: "What standard does this service achieve?"
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research - may involve evaluating or comparing interventions, particularly new ones. Qualitative research - usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or	Usually involves analysis of existing data but may include administration of simple interview or questionnaire	Usually involves analysis of existing data but may include administration of simple interview or questionnaire

investigations additional to routine care		
Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical audit.	No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation.
May involve randomization	No randomization	No randomization
ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:		
RESEARCH REQUIRES ISERC REVIEW	AUDIT DOES NOT REQUIRE ISERC REVIEW, unless results are to be published in a scientific journal or disseminated beyond the host institution.	SERVICE EVALUATION DOES NOT REQUIRE ISERC REVIEW, unless results are to be published in a scientific journal or disseminated beyond host institution.

Appendix ii: Application to Involve Human Participants in Research – Infonetica Ethics Review Manager Form

APPLICATION TO INVOLVE HUMAN PARTICIPANTS IN RESEARCH

INSTITUTIONAL SCIENTIFIC ETHICS REVIEW COMMITTEE (ISERC) THE AGA KHAN UNIVERSITY - KENYA

The contents of the Application for Scientific and Ethics Review Form are

Contact Information of the Applicant and Principal Investigator

- Title _____ _____

  First name Surname

  (Full Names)

  Department _____

  Designation _____

  Telephone _____ Mobile _____

  Address

  P.O. Box _____Code_____, Tel. _____ ext. _____

  Email: _____

Date:

Contact Information of the Co- Investigators (Ability to add up to 5 co-investigators)

- Title _____ First name _____ Surname _____

  Institution of affiliation _____

  Designation _____

  Country _____

  Telephone _____ Mobile _____

  Address

  P.O. Box _____Code_____, Tel. _____ ext. _____

  Email: _____

GENERAL INFORMATION

Title of the Research Project: _____

Key Words: _____

- Please upload the Principal Investigators certificate from any of the following programs.
    - CITI Program
    - GCLP
    - GCP
    - Any Other (Specify)
- Please upload the Principal Investigators certificate from any of the following programs.
    - CITI Program
    - GCLP
    - GCP
    - Any Other (Specify)
- Indicate the **Proposed Date** of starting the study_____

  Note*: The commencement date is the date the researcher expects to actually begin interacting with human participants (including recruitment). The completion date is the date that the researcher expects that interaction with human participants, including follow-up, will be complete*.)
- Indicate the **Proposed Date** when the study will reach completion: _____
- Is this study a funded Yes_____ No_____?
- What is the source of funding for this study?

  Department fund

  URC

  Seed money

  External grants (Please specify)

Period of Funding: _____(dd/mm/yy) _____ to: _____(dd/mm/yy)____

- Location/s where the research will be conducted: _____

.**11**. **Level of the Project**

Faculty

Staff Research

PhD Thesis

Master's Thesis

Undergraduate research

Other (please specify): _____

SUMMARY OF THE PROPOSED RESEARCH

12. **Rationale**

Describe the purpose and background rationale for the proposed project, as well as the hypotheses (is)/research questions to be examined.

Why are you doing this study (Study rationale?)
What are your study objectives?
Significance/justification:
Research questions:

13. **Methodology**

Describe sequentially, and in detail, all procedures in which the research participants will be involved (e.g., paper and pencil tasks, interviews, surveys, questionnaires, physical assessments, physiological tests, time requirements etc.)

Note: Attach a copy of all questionnaire(s), interview guides or other test instruments.

Study Design

Sample size

Source Population

Sampling strategy and enrollment method

Inclusion and exclusion criteria

Study design

Methods of Data Analysis

14. **Participants**

Describe the number of participants and important characteristics (such as age, gender, location, affiliation, inclusion/exclusion etc.)

What Intervention / interaction will the research subject undergo if they enroll in this study? Please state in detail.

What is the duration of an individual subject's participation, including follow-up

evaluation if applicable? Please include the number of interactions with each participant.

Where will the interaction/intervention with the research participants take place?

APPLICATION FOR ETHICS REVIEW COMMITTEE APPROVAL

15. Type of Approval

Please indicate whether you are applying for ERC exemption or full committee review or your study has been approved by the previous ERC?

- Exemption

ii. Full committee review
iii. Expedited review
iii. Approved by an ERC in Kenya

16. Other Research Ethics Committee/Board/IRB Approval

- Is this a multi-centred study? **Yes No**
- Has any other institutional Ethics Committee/Board approved this project? **Yes No**

17. If **Yes**, please provide the following information:

Title of the project approved elsewhere: _____
Name of the Other Institution: _____
Name of the Other Board: _____
Date of the Decision: __/___/_____
Attach copy of the clearance certificate / approval: _____

- Will any other Research Ethics Board be asked for approval? **Yes** **No**

If **Yes**, please specify:

_____

18. **Conflict of Interest**

- Will the researcher(s), members of the research team, and/or their partners or immediate family members:
  - Receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, etc.) as a result of or connected to this study? **Yes No**
  - If **Yes**, please describe the benefits below. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are integral to the general conduct of research.)

- Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that the sponsor has placed on the investigator(s).

- Discuss the possibility of commercialization of the research findings., in any

19. **Experience**

What is your experience with this kind of research?

20. **Recruitment**

- Describe how and from what sources the participants will be recruited, including any relationship between the investigator(s) and participant(s) (e.g., instructor-student; manager-employee).

Note: Attach a copy of any poster(s), advertisement(s) or letter(s) to be used for recruitment.

- How and where will you contact these participants?
- Time required of participants: on occasion(s).
- Are participants proficient in the language in which the survey is being conducted?

Yes No

If not, is translation available?

If **No** to either of above, please provide details.

Yes No

21.**Compensation**

Will participants receive compensation for participation?

- Financial **Yes** **No**
- Nonfinancial **Yes** **No**

If **Yes** to **either** i) or ii) above, please provide details.

- If participants choose to withdraw, how will you deal with compensation?

DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

22. **Possible Risks**

- Indicate if the participants might experience any of the following risks:
- **P**hysical risk (including any bodily contact or administration of any substance)?
  Yes No
- Psychological risks (including feeling demeaned, embarrassed worried or upset)?
  Yes No
- Social risks (including possible loss of status, privacy and/or reputation)?
  Yes No

- Is there any deception involved?
  Yes No
- Are any possible risks to participants greater than those the participants might encounter in their everyday life? Yes No
  - If you answered **Yes** to any of points i) through v) above, please explain the risk.

- Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used).

23. State all the measures that you will take to mitigate the risks

Possible Benefits

Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific community/ society that would justify involvement of participants in this study.

THE INFORMED CONSENT PROCESS

24.**The Consent Process**

- Describe the process that the investigator(s) will be using to obtain informed consent, including a description of who will be obtaining the informed consent. If there will be no written consent form, explain why.

Note: Attach a copy of the Project Information Sheet(if applicable), the Consent Form (if applicable), the content of any telephone script (if applicable) and any other material which will be used in the informed consent process.

- Will the information provided to the participants be complete and accurate?

  Yes No

  If no, please describe the nature and extent of the deception involved. Include how and when the deception will be revealed, and describe the specialized training of the person who will administer this feedback. It is recommended that participants have the opportunity to sign a second consent form, following debriefing when the deception is revealed, to ensure a fully informed consent.

  Note: Attach a copy of the debriefing feedback and, if necessary

25. **Consent by an authorized party**

If the participants are minors or for other reasons are not competent to consent, describe

the proposed alternate source of consent, including any permission / information letter to be provided to the person(s) providing the alternate consent.

26. **Alternatives to prior individual consent**

If obtaining individual participant consent prior to starting the research project is not appropriate for this research, please explain and provide details for a proposed alternative consent process.

27. **Participant feedback**

Explain what feedback/ information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, or access to the results of the research).

Note: Please provide a copy of the written information, if applicable.

28. **Participant withdrawal**

- Describe how the participants will be informed of their right to withdraw from the project. Outline the procedures that will be followed to allow the participants to exercise this right.

- Indicate what will be done with the participant's data and any consequences for the participant of withdrawing from the study.

- If the participants will not have the right to withdraw from the project, please explain.

CONFIDENTIALITY

29. What records, data or human biological specimens will you be using?

Data already collected from another research study

Data already collected for administrative purposes (e.g. hospital discharge data)

Medical records

Electronic information from the clinical database

Patient specimens (tissues, blood, serum, surgical discards, etc)

Other

30. For each of the data sources describe the methods you will use to uphold confidentiality

_____

31. Does this research involve AKUH patients?

Yes _____

No _____

- Will all participants be anonymous? **Yes No**
- Will all data be treated as confidential? **Yes No**

(Please note the difference: Participants' identity/data will be confidential if an assigned ID code or number is used, but it will not be anonymous. Anonymous data cannot be traced back to an individual participant.)

- Describe the procedures to be used to ensure anonymity of participants and/or confidentiality of data both during the conduct of the research and in the release of its findings.

- Explain how written records, video/audio tapes and questionnaires will be secured, and provide details of their final disposal or storage.

- If participant anonymity or confidentiality is not appropriate to this research project, explain, providing details of how all participants will be advised of the fact that data will not be anonymous or confidential.

35. How will soft and Hard data be transmitted among research personnel?
    - Secure network
    - Password access
    - Data Encryption
    - Password protected file(s)
    - Automatic log-off
    - Data de-identified by the research team
    - Locked cabinet
    - Data coded by the research team with a master list secured and kept separately
    - Others (Specify)_____
36. With Whom will the data be shared with – outside the immediate AKU research team? For each, explain confidentiality measures.
37. Will data be transferred outside the AKU? Yes_____ No_____

    If yes- answer number 38, If no – jump to question 39
38. Are data transfer agreements in place? Yes _____ No _____
39. Will Human biological samples be transferred outside the AKU?

Yes_____ No _____

40. Are material transfer agreements in place Yes_____ No_____
41. Will subjects specimens be stored for future research?

Yes _____ No_____

42. Describe your plans for disposition of data and /or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended.

MONITORING ONGOING RESEARCH

43. **Adverse events** (unanticipated negative consequences or results affecting participants) must be reported to the ISERC as soon as possible and not more than 48 hours after occurrence.
44. **Additional Information**

    (Use an additional page if more space is required to complete any sections of the form, or if there is any other information relevant to the project that you wish to provide to the ISERC)

DOCUMENT SUBMISSION

Please attach your study protocol. (upload document)

Please upload your study questionnaire (English)

Please upload your study questionnaire (available in any other language)

Please upload the Materials Transfer Agreement (English)

Please upload the Data Transfer Agreement (English)

Please upload the NACOSTI permit (if applicable – If not yet issued, upload as soon as it is available)

Brief curriculum vitae (Upload for all Investigators/ Supervisors/ Students Involved)

Recent publications list: As a word document upload a list of the most important and relevant publications or presentations over the last five years (papers in press or submitted for publication are also acceptable). *Please give full bibliographic reference [authors, title, journal, volume, page numbers, and year].*

SIGNATURES

Principal Investigator Assurance:

As a Principal Investigator/Primary Supervisor, I _____ have the ultimate responsibility for the conduct of the study, including performance of the project and protection of the participants. I have read and am responsible for the content of this application. If any changes are made in the above arrangements of procedures, or adverse events are observed, I will bring these to the attention of the ISERC.

Signature of Principal Investigator/Primary Supervisor **Date**

Appendix iii: Progress Report Form

INSTITUTIONAL SCIENTIFIC AND ETHICS REVIEW COMMITTEE (ISERC) THE AGA KHAN UNIVERSITY - KENYA PROGRESS REPORT

(ISERC Ref. No) **REPORT DATE (**from - to**)**

URC **Seed Money** **External Funded**: **Local** **Overseas**

FUNDING AMOUNT: **PERIOD** (from & to):

Project Title: _____Principal Investigator _____
(*Or Reported By***)**

Project Commencement Date:

1. If the project has not commenced, or commencement delayed, advise when the project is expected to commence or whether the project is to be withdrawn or what is the reason for delay in starting the project work?

2. Is the project complete? Yes No

3. If, yes, give date :

4. Give a brief report of progress and results to date, if any, problems encountered actions taken to solve the problems, if any and include a list of publications, if any (attach a separate page if necessary).

5. Details of progress reports (if any) submitted earlier.

Report No	**Period Covered**	**Phase Wise Completion Of The Work Plan**	**Date Of Submission**	**Remarks**

6. Has the project been conducted in accordance with the protocol approved by the Research Committee and Ethics Committee Yes_____No_____
If no, please give details._____
a) Were there any serious adverse events? Yes _____ No____ Not Applicable_____

If **yes**, please details (Add extra rows if needed and attach copies of the adverse reports)

Adverse Event Details	Action Taken (In details)	Occurrence Date	Study/Not Study Related	Date reported to ISERC	Date reported to Hospital Patient Safety Committee

b) Where there any other Unanticipated Adverse Events

Adverse Event Details	Action Taken (In details)	Occurrence Date	Study/Not Study Related	Date reported to ISERC	Date reported to Hospital Patient Safety Committee

7. (a) Are you proposing any modification in the original protocol or methodology, or work plan?
Yes _____No _____

If **yes**, please detail reasons for modifications.(Add extra rows if needed and attach (i) revised proposal tracking the modifications (ii) clean copy of the revised proposal)

Item	**Original Text & Page**	**Modification made & Page**	**Explanation for Change**

(b) Are you proposing any change and/or addition of the Investigators?

Investigator Details	**Explanation for Change**

7 . Has the ISERC approval period expired?
Yes _____ No _____
If **yes**, do you wish to apply for an extension of the approval period?
Yes _____ No _____

If **yes**, please state the new expiry date requested and the reason for request for extension.

New expiry Date Requested	**Reasons for Extension**

9. Please remember that any amendments to the approved protocol require further specific approval by the ISERC

I confirm that this research project is in conformity with the requirements of sponsor and the approval of the ISERC and (and subject to any changes subsequently approved) and that all amendments are already reported to the ISERC.

All financial matters are dealt according to the Grants Support Office (GSO) guidelines.

Principal Investigator/Primary Supervisor:
Name: _____ Signature: _____

Department: _____Date _____

Department Chair:
Name: _____ Signature: _____

Department: _____ Date:_____

Appendix iv: ISERC General Ethics Review Evaluation Form

INSTITUTIONAL SCIENTIFIC AND ETHICS REVIEW COMMITTEE (ISERC) OF THE AGA KHAN UNIVERSITY – KENYA

GENERAL RESEARCH ETHICS REVIEW EVALUATION FORM

Application No: year/ISERC- ….

Title:_____

		Yes	No	N/A	Comments
	Is all the documentation provided?				
	Scientific importance and validity				
1	Will the study lead to a) improvements in human health and wellbeing? b) Increase knowledge?				
2	a) If the study is a replication of a previous study, b) If YES above, Is it justified (mention in comments)?				
3	If this is an intervention study, can it be practically implemented?				
4	Is there provision for dissemination of results of the research?				
5	a) Has the research protocol been approved by a Scientific Committee/ body? b) Has the research proposal been approved by an accredited Ethics body/ISERC/IRB?				
6	Are the objectives stated clearly?				
7	Is the study design appropriate in relation to the objectives?				
8	Is the study designed using accepted principles, methods and practices?				
9	Is there a plausible data analysis plan?				
10	Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of research participants?				

		Yes	No	N/A	Comments
11	Are the investigators qualifications, competence and experience appropriate to conduct the study?				
12	Are the facilities at the site adequate to support the study?				
13	Is the manner in which the results of research will be reported and published ethical?				
	Assessment of Risks/Benefits				
1	Is the involvement of human participants necessary to obtain the necessary information?				
2	Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
3	Are there any plans to withdraw or withhold standard of care for the purpose of research and such actions if any justified?				
4	Is the proposed standard of care in keeping with best local practices?				
5	Is the medical and psychological support for the participants adequate?				
6	Does the study site have adequate support staff, facilities and required emergency procedures?				
7	Is there provision for compensation for participants who sustain research related injuries?				
8	Have adequate provisions been made for dealing with and reporting adverse events?				
9	Have adequate provisions been made for safety monitoring and termination of the research project?				
10	Is there a possibility of an intervention being available to the population if found effective?				
	Respect for the dignity of the research participants				
	Informed consent				
1	Is the process for obtaining informed consent appropriate?				
2	Do participants have the capacity to consent?				
3	Is the justification for the intention to include individuals who cannot consent adequate?				

4	Are the arrangements for obtaining surrogate consent or assent for such individuals appropriate?				

		Yes	**No**	**N/A**	**Comments**
5	Will refusal to participate be respected?				
6	Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable? Include an assessment of language level with the proposal e.g. FOG index				
7	Do you approve the compensation offered?				
8	Is the consent given voluntarily?				
9	Will fresh informed consent be obtained if the procedures are changed during the research?				
10	Is there an opportunity for the participant to ask questions regarding the research?				
	Confidentiality				
1	Is the privacy of the research participant safeguarded?				
2	Are data/ biological specimen storage and disposal procedures adequate to protect participant confidentiality?				
	Rights of the participants				
1	Is the participant's right to unconditionally withdraw from the research at any time safeguarded?				
2	Is there provision for the participants to ask questions and register complaint?				
3	Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
4	Is there provision for the subjects to be informed of results of research?				
5	Is there provision to make the study product available to the participants following research?				
	Fair participant selection				

1	Has the study population been determined, primarily, based on the scientific goals of the study?				
2	Is the selection of participants appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				

		Yes	**No**	**N/A**	**Comments**
3	Does the selection of participants stigmatize any group?				
4	Does selection of subjects favour any group?				
5	Is the initial contact and recruitment appropriate?				
6	Is the research conducted on vulnerable individuals or groups? E.g. children, prisoners, pregnant women, handicapped, mentally disabled persons				
7	Is the research externally sponsored?				
8	Is the research a community research?				
9	Is the research a clinical trial?				
	Responsibilities of the researcher				
1	Has the researcher followed any applicable legal regulations or other guidelines?				
2	Has the researcher obtained permission from the relevant authorities?				
3	Are there any other ethical / legal/ social /financial issues in the study?				
	Vulnerable group e.g. children, prisoners, pregnant women, handicapped, mentally disabled persons				
1	Can the research be equally well carried out in another, less vulnerable, group?				
2	Will the study result in new knowledge relevant to the health needs of this population?				
3	Is the procedure for obtaining proxy/surrogate consent adequate?				
4	Will the subject's withdrawal from research due to refusal (dissent) be always upheld?				
5	Does the study benefit outweigh the risk?				

6	Will the benefit of the research be made available to this group?				
	Externally sponsored research				
1	Is there a local co –investigator?				
2	Has the research project been approved by a ERC/ IRB in the sponsoring country?				
3	Is the justification for the research to be carried out in Kenya and not in the sponsoring country/institution adequate?				

		Yes	**No**	**N/A**	**Comments**
4	Are the post-research benefits to Kenya acceptable?				
5	Are relevant local laws/ regulations/guidelines of each country adhered to?				
6	Is the research responsive to cultural/social differences?				
7	Are participants receiving the best current treatment as part of the protocol?				
8	Are the provisions for intellectual property sharing fair?				
9	If the data/biological materials are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights? Ref to Material Transfer Agreement				
10	Is there provision for results of research to be conveyed to relevant authorities in AKU, EA?				
11	Are there any conflicts of interest? If yes, provide details?				
12	Is there a written agreement between the collaborators?				
	Community based research				
1	Is the study relevant to the needs of the community?				
2	Is the study culturally acceptable?				
3	Does the research study in any way stigmatize the participants?				
4	Before commencement of the study, have the concerne community leaders and other key stakeholder been consulted to consent to design of the study?				
5	Is community consent obtained?				

6	Is individual consent obtained?				
7	Is the privacy of the participants safeguarded?				
8	If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?				
9	Will the intervention or product developed or knowledge generated be made available and affordable for the benefit of the population?				
10	Does the research contribute to capacity building of the community?				

		Yes	**No**	**N/A**	**Comments**
11	Will the results of the research be made available to the concerned community leaders and other key stakeholders in the community?				
12	Are any conflicts of interest resolved?				
	Clinical trials				
1	If it is a multicentre trial, are all centres following the same protocol?				
2	Is the clinical trial registered with a clinical trials registry?				
3	Have adequate animal toxicity and teratogenicity trials been carried out?				
4	Is their sufficient justification for using a placebo control arm?				
5	Does the control group receive the standard therapy?				
6	Are all subject participants treated equally?				
7	Is the procedure for dealing with adverse events adequate?				
8	Is the procedure for reporting adverse events adequate?				
9	Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?				
10	Are the criteria for termination of the trial detailed?				

11	Is there provision for insurance of trial participants?				

Summary of comments

Risk Level:	High	Medium	Low
Recommendation:	Approve	Resubmit (please state conditions)	Disapproved

Appendix v: Exemption from Full Committee Review Procedure

INSTITUTIONAL SCIENTIFIC AND ETHICS REVIEW COMMITTEE (ISERC) THE AGA KHAN UNIVERSITY – KENYA

PROCEDURE FOR ISSUE OF EXEMPTION LETTER BY ISERC FOR SELECTED STUDIES

The studies in which human subjects are not involved directly, or no intervention is done are often exempted from full AKU- ISERC review. It is a requirement by NACOSTI that all research work done in Kenya Since majority of journals ask for approval by an Institutional Review Board or by AKU-ISERC before accepting a manuscript for publication, it is necessary that the researchers get an approval or an exemption letter from ISERC *before* starting the study, as it is unacceptable for ISERC to review studies retrospectively. It is the responsibility of researchers to obtain such a letter before any study is started.

This point is again restated for emphasis: even if studies fall in the exemption category, they still need to be submitted to ISERC for obtaining a letter of exemption prior to the commencement of the study as ISERC does not allow retrospective review of studies, even for the purpose of publication. A system should be put in place in Unit/ departments whereby studies are signed-off by the Unit Head/ Departmental Chair prior to their commencement. This precautionary safeguard has been advised by the University Research Council to ensure that no controversial or sensitive studies are conducted even though they may have obtained clearance from relevant AKU subcommittees.

The following procedure has been developed for seeking an *exemption letter* from ISERC for a study, if it is determined that the study falls in the exemption category based on the stated guidelines.

1. Procedure for Submitting Applications:

1.1. Each department will set up a Departmental Research/ Review Committee (DRC).

1.2. The researcher will submit his/ her proposal to the DRC.

1.3. The DRC will review the proposal and send its recommendation to AKU-ISERC on the prescribed form (attached).

1.4. The proposal along with the DRC's recommendation will be submitted electronically to AKU- ISERC secretariat along with one hardcopy.

1.5. The recommendations will be reviewed by Chair of ISERC. If no ethical issue is found,

the Chair of ISERC will issue a letter of exemption within seven days of receipt of the recommendation.

1.6. In case Chair of ISERC is not satisfied with recommendation, full proposal will be asked for review in the AKU-ISERC committee.

1.7. No study on human subjects will be done in any department (including students, residents or faculty) without obtaining exemption or approval from AKU-ISERC.

2. Exempt Research Under the Revised 2018 Common Rule

(Adopted from Guidelines for Ethics Review Committee Pakistan)

In line with the revised 2018 US guidelines of ethical review of research studies that are known as COMMON RULES, the Ethical Review Committees (ERCs) of FHS, AKU have updated their criteria for classifying research studies as exempt from review. These criteria are listed below. The Institutional Ethics Review Committee (ISERC) Kenya has thus adopted these guidelines to be in compliant with the overall University guidelines.

Even when research is exempt from further requirements of review and reporting, basic ethical standards still apply.

- Except in the case of chart reviews or database research, potential subjects must be provided enough information to be able to choose whether or not to participate. The information would typically include the voluntariness of their participation, the purpose of the research, the nature of the subject's involvement, time commitments, and contact information for the investigator.
- Research data must be handled and stored securely, in compliance with university policy.
- Access to research data must be limited to study team members and other authorized personnel.
- All members of the research team must be current on human subjects training and must have a current conflict of interest disclosure.

Please note that the researcher CANNOT himself or herself decide if the research project is exempt. The application for exemption still must be made via ISERC chair who will decide if the project is exempt or not as per procedure for submitting Applications. Each exempt category is described below.

2.1. EXEMPT CATEGORY 1:

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Most educational research on regular and special educational instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods may be exempt under this category.

There must not be any impact of subject's opportunity to learn or any negative impact if the research involves an evaluation of the instructors. If the research involves significant time and attention away from the delivery of regular curriculum or withholding of standard educational content, this exemption would not apply. Also, there must be protection against negative impact on employment if instructors are being evaluated. Research involving randomization to a unproven educational technique, or research conducted by supervisors involved in employment decisions may not be approvable under this exemption.

Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children may be eligible for this exemption.

2.2. EXEMPT CATEGORY 2:

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an ISERC conducts a limited ISERC review.

This category involves interactions (verbal and written responses) and data collection only. The data collection can include audio or video recordings. Research involving "interventions" would not be approvable under this category. Interventions include manipulation of the environment or physical procedures to collection information, such as a cheek swab.

Applicability to vulnerable populations

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption.
- The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption only when it related to educational tests or observations in which the investigators don't participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited ISERC review.

2.3. EXEMPT CATEGORY 3:

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audio-visual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an ISERC conducts a limited ISERC review.

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Applicability to vulnerable populations:

- Pregnant women who are adults may be included in this type of research
- Research that targets a prisoner population is not eligible for this exemption.
- Research that could include children is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.

- Research involving decisional impaired persons is not eligible for this exemption.

2.4. EXEMPT CATEGORY 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio-specimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable bio-specimens are publicly available;

(ii) Information, which may include information about bio-specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is for health care operations or for public health activities and purposes

- The requirement that all study data be existing at the time of ISERC submission has been eliminated. Data under this exemption may be both retrospective and prospective.
- The requirement that the study involves data only has been eliminated. The research may also involve the use of specimens.

It is important to note the Exemption Category 4 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another approval path would be required.

Applicability to vulnerable populations:

- Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn't

designed to recruit prisoners and prisoners were only incidental subjects of the

research.

- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

2.5. EXEMPT CATEGORY 5

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio-specimens was obtained

(ii) Documentation of informed consent or waiver of documentation of consent was obtained

(iii) An ISERC conducts a limited ISERC review and makes the determination that the research to be conducted is within the scope of the broad consent

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

Research with vulnerable populations may be approvable with this exemption:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

Acknowledgement: ERC FHS Pakistan gratefully acknowledges the permission of University of Kansas Medical Center to use their following document as a resource used to draft this AKU FHS ERC document.

http://www.kumc.edu/Documents/hrpp/Topical%20Guidance/KUMC%20Guidance%20Document%20for%20Exempt%20Research%202018%20Common%20Rule%20Changes.pdf

3. Composition of Departmental Review Committee:

3.1. The Departmental Review Committee (DRC) should consist of at least three members; each member should have

3.2. Obtained at least one grant from the Dean/ Director, URC or external sources. In case of an external grant he/ she must have written the research proposal himself/ herself.

3.3. Have published at least one paper in an international journal.

3.4. Obtained a certificate in on-line courses on research ethics. This could be AKU-ISERC research ethics course or any international ethics research course.

4. Terms of Reference of a Department Review Committee

4.1. Review the proposal for its scientific content

4.2. The following points should specially be considered during scientific review:

4.3. Rationale/justification for the study is given.

4.4. Research question is clearly defined.

4.5. The objectives of the study are clear and achievable.

4.6. Clear analysis plan is given indicating what statistical tests will be applied for different variables of interest.

4.7. Other points/ criteria as may seem to be necessary.

5. Review of a proposal for ethical issues

The following points should specially be considered during ethical review:

5.1. The researcher is directly involved in the care of the patients if the data is collected from patient's charts. In case of students'/ residents' research, his/ her supervisor is involved in the care of such patients.

5.2. In case the data is collected about a group of patients who are managed by more than one physicians, the other concerned physicians are also taken into confidence. They may or may not be a co-investigator in that research proposal.

5.3. In case of a multidisciplinary research proposal, all the stakeholders are taken into confidence.

5.4. The data to be collected does not contain any sensitive information of a financial, sexual nature etc. without the express permission of the patients.

5.5. Only data that is relevant to the study questions and objectives is to be collected. Collection of unnecessary data is to be avoided.

5.6. No photographs of patients are to be used without written permission of the patient/ guardian.

5.7. Informed-written or witnessed-verbal consent is obtained, if additional information other than that for routine clinical care is to be collected.

5.8. No intervention is planned in case of prospective review of patient data.

5.9. In case any intervention is planned, funding is available. Such proposals should be submitted for detailed ethical review to AKU-ISERC.

5.10. Prospective epidemiological studies including KAP surveys, filling up of questionnaires and interviews must have a written/ witnessed informed consent form. In case of student/ residents' research as part of their curriculum (such as dissertations) such proposals should be reviewed by the Departmental Review Committee, and submitted to AKU-ISERC with a recommendation for expedited approval. However, in case of faculty and other researchers, such proposals should be submitted to AKU-ISERC for full ethical review and approval.

5.11. In case of analysis of laboratory/ radiological data, the data is not linked with the patient's profile.

5.12. No new tests are performed on stored laboratory samples especially genetic tests, without taking fresh consent from the donor of the samples.

5.13. In case of linking retrospective laboratory/ radiological data with clinical data, the relevant clinical departments/ physicians are taken into confidence.

5.14. In cases of linking prospective laboratory/ radiological data with clinical data, not only the relevant clinical departments/ physicians are taken into confidence but informed consent is obtained from the relevant patient/ guardian.

5.15. Researchers from laboratory/ radiology do not contact the patients directly for obtaining additional information for research purpose without taking the primary physician into confidence.

Appendix vi: Departmental Research Review Committee Form

Chair of the Committee

The above study has been reviewed by the Departmental Research/ Review Committee (D/SRC). The Committee members are satisfied that the study falls in the exemption category and has no ethical issue. The study is being submitted to ISERC for granting of an exemption letter.

Name of DRC Chair

Signature

Date

Name Department Chair

Signature

Date

For ISERC

Exemption granted	**Yes**	**No**	**Signature of Chair ISERC**
If not, then state the reasons			
Has the PI been informed about decision of ISERC?			
If yes, has any response been received?			
If yes, has the response been reviewed by the Chair of ISERC?			
If yes what decision was taken? Was exemption granted?			

Appendix vii: Non Compliance Reporting Form

INSTITUTIONAL SCIENTIFIC AND ETHICS REVIEW COMMITTEE (ISERC) OF THE AGA KHAN UNIVERSITY – KENYA

This non- compliance reporting form will only be used to report **observed or apparent noncompliance**.

Noncompliance Includes, but are not limited to, failure to obtain ISERC approval, inadequate supervision, failure to follow recommendations made by ISERC, failure to report unanticipated problems or protocol changes, etc.

Principal Investigator and Co – Investigators Contact Details:

Name:

Phone:

E-Mail:

Additional/ other relevant Study Contacts

Name:

Phone:

E-Mail:

Project Title:

Sponsor/Funding Agency:

Sponsor Number:

This study is:

Open to enrollment

Closed to enrollment

State the number of active participants in the study as at the date of submission

_____

Provide an explanation of the facts surrounding the noncompliance including the timeline from discovery to reporting. Describe how the non-compliance was discovered.

_____

_____

Provide an assessment of the increased risk (if any) to participants resulting from the noncompliance.

_____

_____

_____

Explain the corrective measures taken in response to the noncompliance and explain any preventive measures that will be takento prevent the noncompliance from occurring in the future (if possible).

_____

_____

Please attach any supporting documentation, such as an audit or monitoring report, etc.

Please indicate any actions that have been taken or are planned to be taken as a result of this non compliance

- The informed consent process/document will be revised. Please submit an amendment requesting the revisions. If theamendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

_____

_____

- The informed consent document will **NOT** be revised. Please explain:

_____

_____

- The protocol will be revised. Please submit an amendment requesting the revisions. If the amendment cannot be submitted atthis time (e.g. requires sponsor approval first), please explain:

_____

_____

_____

- Currently enrolled subjects will be notified. Please attach a copy of the notification.

_____

_____

- Other corrective and/or preventive action will be taken. Please explain:

_____

_____

- The event compromised the validity of the data. Please explain:

_____

_____

By submitting this form, the Principal Investigator assures that all information provided is accurate. He/she assures that procedures performed under this project was conducted in strict accordance with Aga Khan University, Nairobi Research policies and procedures, the ISERC approval and all has adhered to principles that govern research involving human subjects. He/she acknowledges that he/she has the resources required to conduct research in a way that will protect the rights and welfare of participants, and that he/she will employ sound study design which minimizes risks to participants. He/she agrees to submit *any* change to the project (e.g. change in principal investigator, research methodology, participant recruitment procedures, etc.) in the form of an amendment for ISERC approval prior to implementation.

_____ _____ _____

Name of the Principal Investigator Signature Date

Appendix viii: Unanticipated Problems/ Adverse Events and Protocol Deviation Reporting Form

INSTITUTIONAL SCIENTIFIC AND ETHICS REVIEW COMMITTEE (ISERC) OF THE AGA KHAN UNIVERSITY – KENYA

Unanticipated Problems/ Adverse Events and Protocol Deviation Reporting Form

This form reports problems that occur during the implementation of investigator or sponsor initiated study suspensions or holds. This form will not be used to report noncompliance. Unanticipated problems should be reported within 48 hours.

- **Principal Investigator and Co – Investigators Contact Details:**

Name:

Phone:

E-Mail:

- **Additional/ other relevant Study Contacts**

Name:

Phone:

E-Mail:

Project Title:

Sponsor/Funding Agency:

Sponsor Number:

- **This study is:**

Open to enrollment

Closed to enrollment

- State the number of active participants in the study as at the date of submission _____
- Provide an explanation of the facts surrounding the occurrence of the unanticipated problem including the timeline from discovery to reporting. Describe how the unanticipated problem occurred.

_____

_____

_____

Adverse Event Report guideline

Describe the reported adverse event which must fulfill the four conditions stipulated below

- Adverse Event that meets the following criteria:
  unexpected (in terms of nature, severity, or frequency) given
  (a) the research procedures that are described in the protocol-related documents, such as the ISERC-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied

ii. Related to participation in the research (i.e., there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)

iii. Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

iv. Requires changes to the research protocol or informed consent process/document or other corrective actions to protect the safety, welfare, or rights of participants or others

Protocol Deviation Reporting guideline

a. Major Protocol Deviation should meet one or more of the following criteria:
   i. May impact participant safety; and/or

ii. Affects the integrity of study data; and/or

iii. May affect a participant's willingness to participate in the study

Examples of protocol deviation: Enrollment of a participant who did not meet all inclusion/ exclusion criteria; performing a study procedure not approved by the ISERC; drug/study medication dispensing or dosing error; or failure to perform a required laboratory test or conducting a study visit outside the required timeframe.

- Change to the ISERC-approved protocol taken without prior ISERC review to eliminate an apparent immediate hazard to a research participant(s) (e.g. purposeful and for participant safety).

  A complaint of a participant that indicates unexpected risks or that cannot be resolved by the research team.
- Publication in the literature, safety monitoring report, interim results, or another finding that indicates an unexpected change to the risks or potential benefits of the research, in terms of severity or frequency.

- Change in labeling or withdrawal from the marketing of a drug, device, or biologic used in a research study.
- Unanticipated adverse device effect (Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants).

- Investigator- or Sponsor-initiated study suspension or hold.

- Other: Please explain

_____

Section iv: Report information

- Date of Report_____
- Date the PI was notified of relevant events: _____
- Study Site/s_____
- Report:

  Initial Report

  Follow-up Report

- Provide a description and explain why the reported matter/s is are determined to be unanticipated problem/s (i.e. How does it/do they meet the criteria for unanticipated problem/s?):
- Explain the immediate corrective action plan to be taken, how this was (or will be) resolved, and whether the sponsor was notified of this (if applicable):

- Explain any prevention plan to prevent recurrence in the future
- Explain any additional actions to be taken in relation to this occurrence

Principal Investigator

Signature: _____Date: _____

Appendix ix: Response to Institutional Scientific and Ethics Review Committee Comments

Response to *Institutional Scientific Ethics Review Committee* comments

To the Chair, Institutional Scientific Ethics Review Committee (ISERC)

Study Title: Author:

(for residents/students only)
DDC Approval for resubmission to ISERC
Signature: ……..

S. #	ISERC comments	Action taken	Page in document

N/B: Provide a detailed point by point response to each recommendation. Where the proposed recommendations have not been incorporated, elaborate in details.

Appendix ix: Checklist for Assessment of Ethical Risks in a Protocol, research involving human participants, machine learning and artificial intelligence

Reviewer's Checklist - Ethics in research involving human participants, machine learning and artificial intelligence

		Findings on ethical risks			**Classification matrix for ethical risks**	**Additional notes/comments**
Area	***Specific topics/questions during review***	***Yes***	***None***	***N/A***	***Low-Medium-High***	
1. Non-discrimination	Are there sources of decision variability that occur in same execution conditions?					
	Does decision variability that occur in same execution conditions affect fundamental rights or ethical principles?					
	Are processes in place to test for biases during development and usage of the system?					
	Is it clear to whom issues related to discrimination can be raised?					
2. Respect for human autonomy	Does the AI system provide useful & necessary information that enables health workers take decisions in full self-determination?					
	Do users have the facility to interrogate algorithmic decisions in order to fully understand their purpose, provenance, and validity?					
	Could the AI system generate confusion for some or all end-users?					
	Are there procedures to ensure that end-users do not over-rely on the AI system?					
	Are there procedures to ensure the AI system does not inadvertently affect human autonomy?					
3. Human oversight vs. AI autonomy	Is a process to allow human control over the AI system, if needed?					
	Are there measures taken to ensure that the AI system always makes decisions that are under the overall responsibility of human beings?					

	Have the humans been given specific training on how to exercise oversight?					
	Are there measures to audit & remedy issues related to governing AI autonomy?					
4. Respect for privacy	Is the personal data information flow in the system under control & compliant with existing privacy protection laws?					
	Are there mechanisms that allow flagging issues related to privacy concerning the AI system?					
	Is it clear how users seek information about valid consent?					
	Is there clear information on the right to withdraw consent and how consent can be revoked?					
	Are there measures to achieve privacy-by-design & default (e.g. encryption, aggregation, anonymization)?					
	Is it clear to whom issues related to privacy violation can be raised?					
5. Technical robustness	***Resilience to attack & security:*** Is the AI system vulnerable to any forms of attack?					
	Is the AI system certified for cybersecurity?					
	Have health workers been well informed on the AI system's duration of security coverage and updates?					
	Are there systems in place to ensure data security and integrity?					
	Could the AI system have damaging effects in case of technical faults?					
	Reliability & reproducibility: Is a strategy in place to monitor & test that the AI meets intended goals & purposes?					
	Are the used algorithms tested with regards to their reproducibility?					
	Are processes for the testing & verification of the reliability of AI systems clearly documented?					
	Accuracy: Are there specific definitions of accuracy applicable to the AI?					
	Are the data used comprehensive enough to ensure accuracy?					
	Are there other data sources that can be used to eliminate bias?					
	Could a low level of accuracy of the AI					

	system result in critical or damaging consequences?					
	Is there a proper procedure for handling the cases where the AI system yields results with a low confidence score?					
	Is there a clear process to ensure that the level of accuracy of the AI system to be expected by health workers is properly communicated?					
	Fallback plan: Are there any alternative plans in case of unexpected results/ AI unavailability or failure?					
	Have fallback plans been defined and tested?					
	Are there governance procedures in place to trigger fallback plans to address AI system errors?					
6. Governance	Is proper governance of data & process ensured?					
	Is an oversight mechanism put in place?					
	Are there clear data governance regulation & legislation applicable to use of the AI system?					
	Is there a designated Data Protection Officer?					
7. Transparency	***Purpose:*** Is it clear who or what may benefit from the product/service?					
	Have the usage scenarios for the AI been specified & clearly communicated?					
	Is there a continuous check on users' understanding of the AI system & output?					
	Is there clear communication on the benefits of the AI system to users?					
	Have the limitations of the AI been specified to its users consistently?					
	Traceability: Are measures in place to inform on the AI system's accuracy?					
	Is the nature of the AI & potential risks communicated in a way that intended users & general public can access & understand?					
	Is a traceability mechanism in place to make the AI system auditable?					

	Are there adequate logging practices in place to record all operations of the AI system?					
8. Design for all (Equitable, diversity, non-discrimination & fairness)	Does the system accommodate a wide range of individual preferences & abilities?					
	Is there consultation with user communities about the correct definition of fairness in use of the AI?					
	Can the AI system be used by those with special needs or disabilities or those at risk of exclusion?					
	Are there processes to ensure avoidance of unfair bias?					
	Are there clear steps and ways of communicating concerns on unfair bias?					
	Is there deliberate engagement of a wide range of stakeholders in design and use of the AI?					
	Are there groups who might be disproportionately affected by the outcomes of the AI system?					
9. Accountability	Is there someone accountable if things go wrong?					
	Do health workers have the skills & knowledge needed for responsible AI utility?					
	Was there provision of appropriate training & disclaimers to users on how to adequately use the AI system?					
	Are there are processes for employees to report potential vulnerabilities, risks or biases?					
	Is there a routine auditing of the AI system by independent teams?					
10. Safety	Are there clear definitions of safety applied in the Project?					
	Have potential safety risks of foreseeable uses of the AI (including accidental or malicious misuse) been identified?					
	Is a process in place to classify & assess potential risks associated with the AI?					

	Is there a plan established to mitigate and/or manage identified risks?					
	Is there a definition of safety criticality levels of the possible consequences of faults or misuse of the AI system?					
11. Societal & environmental well-being	Is the AI system beneficial to human beings, including future generations?					
	Does the AI system impact human work and work arrangements?					
	Does the AI system create the risk of de-skilling of the workforce?					
	Is there provision of continuous training opportunities and materials for up-skilling?					
	Is the AI sustainable?					
	Are there potential negative environmental impacts of the AI system?					

Appendix x: AKU - ISERC Team of Reviewers

INSTITUTIONAL ETHICS REVIEW COMMITTEE (ISERC)
THE AGA KHAN UNIVERSITY - KENYA

This SoPs were revised and updated by;

Dr. Christopher Opio	ISERC Chair
Dr. Caroline Kithinji	ISERC Vice Chair
Prof. Sheila Shaibu	ISERC member
Dr. Karatu Kiemo	ISERC member
Mr. Ambrose Rachier	ISERC member
Mr. James Orwa Kenyatta	ISERC member
Dr. John Weru	ISERC member
Dr. Daniel Maina	ISERC member
Prof. Violet Naanyu	ISERC member
Rev. Philip Noel Owuor	ISERC member
Mr. Githieya Kimari	ISERC member & Lay Person representative
Ms. Winnie Munene	Research Admin Manager / Secretary to the ISERC
Prof. William Macharia	Associate Dean Research and Professor, AKU

Appendix xi: Bibliography

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