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1. PREAMBLE

1.1. Inevitably, the search for new knowledge, innovation and collaboration raises questions of an ethical nature. The Aga Khan University (AKU) in Kenya recognises the need for the development of human capacities through the discovery and dissemination of knowledge, and application through service in a socially responsible context.

2. POLICY

2.1. Aim and purpose of the SoPs

2.1.1. This Standard Operating Procedures (SoPs) sets out the requirements for ethics review and approval at the AKU 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 SoPs should be read in combination with AKU 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 Mechanism for Change of Principal Investigator
- Extramural Grant Application Policy (Pre-award)
- Policy and Guidelines for Intramural Funding

2.2. Ethical Requirements of Clinical Research

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

2.2.1. Social or scientific value

2.2.1.1. Clinical research must be valuable
2.2.1.2. Evaluates diagnostic/therapeutic interventions
2.2.1.3. Lead to improvements in health and well being
2.2.1.4. Test or hypothesis should generate important knowledge
2.2.1.5. Dissemination of clinical research results (plans to publish/present in conferences)
2.2.1.6. Clinical research with non-generalizable results are not socially/scientifically valuable

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

- Scientific goals of the study, (not vulnerability or privilege) be the primary basis for determining groups/individuals to be recruited
- Results must be generalizable
- Subject selection can affect Risk-Benefit ratio of the study
- Subjects be selected to maximize benefits to individuals/society and minimize risks

2.2.4. Favourable 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 enrol and participate in clinical research only when the research is consistent with their values, interests, and preferences

2.2.5.2. To provide I/C 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 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 favourable 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 IERC 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 foetal material, embryos and tissues from the recently dead, shall be reviewed by the AKU Kenya IERC. 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 IERC.

2.3.3. The IERC 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. IERC 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 IERC 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 IERC 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.

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

[1] 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.

2.6. Status of the Kenya IERC 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 rigour, efficiency and relevance to the geographical and disciplinary context, the AKU has adopted a two-tiered ethics review 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 ERB has devolved the power of ethics clearance to Ethics Review Committees (ERCs) created as sub-committees of the ERB. The IERC in Nairobi, Kenya is one of the AKU IERCs and reports to the ERB through its chair.

2.6.4. As a sub-committee of the AKU ERB, the IERC 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 IERC is accountable to the AKU ERB and NACOSTI.

2.7.2. The IERC 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 IERC may from time to time bring to the attention of the ERB issues of significant concern.

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

3. COMPOSITION

3.1. Membership

The Kenya IERC composition is adopted from the NACOSTI guidelines for accreditation of ethics review committees in Kenya (Version March 2017). The membership of the IERC 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 IERC 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 IERC 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 IERC, 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.

3.2.2. However, in those circumstances (3.2.1), there must be at least 50% of the members physically 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 normally reviewed by the IERC

3.2.3. The IERC shall be free to consult any person(s) considered by the IERC 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 IERC shall be the responsibility of the administrative faculty research head of the Office of the Associate Dean of Research in Kenya in consultation with Chair of IERC.

3.3.2. New members of the IERC 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 IERC

3.3.3. Appointments will be on voluntary basis.

3.3.3. Appointments shall allow for continuity, development of expertise within the IERC, 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 faculty research head of the Office of the Associate Dean of Research in Kenya; in consultation with the IERC chair.

3.4.2. The Chairperson and the Vice Chair are appointed for a period of three years and may be reappointed at the discretion of the administrative faculty research head of the Office of the Associate Dean of Research in Kenya

3.4.3. Administrative Manager (Research) shall be secretary to the committee with no voting power.

3.4.4. The administrative faculty research head of the Office of the Associate Dean of Research in Kenya may terminate a members tenure due to:

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

3.4.5. A member may resign from the IERC at his or her own volition by giving notice in writing to the Chairperson. The chair will provide such notice to the faculty research head of the Office of the Associate Dean of Research on 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, IERC meeting attendance responsibilities and general responsibilities as an IERC 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, members shall be provided honorarium for legitimate expenses incurred in attending IERC meetings or in otherwise carrying out the business of the IERC

3.5.3. Members by accepting an appointment commit to ensure

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

3.6. Education for IERC members

3.6.1. Newly appointed members shall be provided with adequate orientation.

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

4. CONDUCT OF BUSINESS

4.1. Procedures

4.1.1. The IERC 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 IERC 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 IERC 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 IERC who has any conflict of interest, financial or otherwise, in a proposal or other related matter(s) considered by the IERC 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 IERC'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 IERC shall endeavour 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.

4.2.5. Advocates and interpreters

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

4.2.7. Where research involves the participation of persons unfamiliar with the English language, the IERC 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.

4.2.8. Attendance of an Observer

4.2.9. An observer or observers may be invited to attend the IERC 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 IERC members on the meeting to be attended by the observer(s).

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

4.2.11. 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.

4.2.12. The IERC 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 IERC Chairperson and shall be subject to the terms and conditions set forth for the attendance as an observer.

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

4.3. Ethical review pathways

4.3.1. Full Review

4.3.1.1. The IERC 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.

4.3.1.2. Based on expertise, IERC 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).

4.3.1.3. 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.

4.3.1.4. During the full 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.

4.3.1.5. 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.

4.3.1.6. 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.

4.3.2. Ratification of approval from another institution/ multicentre research

4.3.2.1. 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

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

4.3.2.3. To facilitate multicentre research the IERC may:

- Communicate with/ rely upon the review of another qualified IERC in Kenya accredited by NACOSTI
- Accept a scientific/technical and/or ethical assessment of the research by another accredited Kenyan IERC 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 administrative faculty research head of the Office of the Associate Dean of Research in Kenya.

4.3.3. Expedited review

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

4.3.3.2. The IERC 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.

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

4.3.4. Exemption from review

*4.3.4.1.*Studies in which human subjects are not involved directly, or no intervention is done shall be exempted from full IERC review process. It is necessary that the researchers get an approval or an exemption letter from IERC *before* starting the study as it is unacceptable for IERC to review studies retrospectively. A procedure has been developed for seeking an *exemption letter* from IERC for a study, if it is determined that the study falls in the exemption category as defined in *Appendix 5: Exemption Procedure*

4.3.4.2.INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)

4.3.4.3.*THE AGA* **KHAN UNIVERSITY - KENYA**

4.3.4.4.PROCEDURE FOR ISSUE OF EXEMPTION LETTER BY IERC FOR SELECTED STUDIES .

4.4. Documentation

4.4.1. For a thorough and complete review, all new applications should be submitted with the following two documents;

4.4.1.1. **Appropriate Application form**

There are two Application Forms prescribed by the IERC. The researcher should complete the form applicable to their type of study

a) Application form to Involve Human Participants in research
b) Application Form for Exemption of Studies from Ethical Review

4.4.1.2. **Full Proposal**

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 IERC
- 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 IERCs 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

4.5. Submissions, notifications and approvals

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

4.5.2. All trainee submissions to IERC shall be processed through the AKU Research Committee 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.

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

4.5.4. The IERC 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.

4.5.5. The Research Office shall circulate the completed application and associated documents received with a meeting agenda to members of the IERC at least ten (10) working days prior to the next meeting.

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

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

4.5.8. 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 IERC support staff

4.5.9. Following its review, the IERC 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.

4.5.10. 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 IERC will remove the application from its agenda and the PI will be expected to reapply.

4.5.11. For resubmissions, the IERC will advise the PI on documents needed, which will include:

a) A detailed point by point response to each recommendation – see Appendix 7: Response to Institutional Ethics Review Committee comments
b) In-text comments/track-changes in the main proposal i.e. using a different font colour, 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 IERC

4.5.12. 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 IERC 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 expertise or equipment or multicentre study where analysis is centralized. The IERC 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 IERC will only give ethics approval for a given proposed research study, the permit/permit to for exportation of the samples will be referred to the Ministry of Health or NACOSTI or relevant national regulatory body for concurrence

4.6.3. Submissions for ethics review that also include a proposal for biological specimens transfer 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 IERC 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 IERC 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 IERC shall require that a similar repository be held at a local-AKU research facility.

4.6.5. The samples/specimens at the overseas coordinating centre must be destroyed within one (1) month of completion of the study. A *memorandum of destruction* of the biological samples or specimens must be submitted to the IERC within three (3) working days of the event.

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

4.6.7. 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

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

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

5. POST-APPROVAL RESPONSIBILITIES

5.1. Follow-up Procedures

5.1.1. The IERC shall monitor approved projects for compliance with the IERC's ethical approval. In doing so, the IERC may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the IERC 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 - Appendix 3: Progress Report Form

5.1.3. The IERC 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 IERC 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 IERC.
  The IERC 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 IERC
- 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 IERC may adopt any additional appropriate mechanism for monitoring as deemed necessary.

5.2. Records

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

- Agendas and minutes of all meetings of the IERC
- Curriculum Vitae (CV) of all members of IERC
- 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 IERC.

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.

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

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

6. COMPLAINTS AND REVIEW

6.1. Complaints concerning the IERC review process

6.1.1. Any complaint concerning the conduct of a research project shall be addressed in writing to the IERC secretary, who upon receipt of such complaint shall promptly notify the chairperson of the complaint. 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 s/he may refer a fresh complaint by way of an appeal to the AKU ERB who shall dispose of the complaint in the manner outlined in section (6.2.4, (6.2.5) and (6.2.6).

6.2. Appeal against the IERC's Rejection of an application for review of a study proposal.

6.2.1. Any person aggrieved by the decision of the IERC rejecting an application for approval of a study proposal may request the chairperson in writing to have such decision reviewed again by the IERC 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 he shall direct the applicant to resubmit the study proposal for further review by the IERC

6.2.3. The IERC shall consider the grounds advanced by the applicant in support of a further review and make a fresh decision after such review. The IERC may invite the applicant to attend the IERC meeting at which a further review is to be conducted and afford him an opportunity to be heard on any matter concerning the study proposal

6.2.4. The IERC may approve or reject the resubmitted study proposal and notify the applicant of its decision within 7 days of the date of the decision and where the study is once again rejected the applicant, if aggrieved by such decision may appeal in writing to the Office of the Associate Dean of Research In Kenya.

6.2.5. The AKU ERB if it considers that the appeal warrants a determination shall constitute a panel to hear and determine the appeal

6.2.6. In arriving at its decision on the appeal the panel appointed by the ERB shall afford both the Applicant and the IERC an opportunity to be heard

6.2.7. The panel after hearing the Applicant and the IERC may:

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

7. REVIEW/AMENDMENT OF TERMS OF REFERENCE

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

7.2. Members of the IERC may from time to time propose changes to the SoPs for review by the IERC. If considered acceptable, such changes shall be forwarded to the URC for approval if appropriate.

APPENDICES

Appendix 1: UK National Patient Safety Agency Classification of Research, Clinical Audit, and Service Evaluation

INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)
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	Usually involves analysis of existing data but may include administration of simple	Usually involves analysis of existing data but may include administration of simple

treatments, samples or investigations additional to routine care.	interview or questionnaire.	interview or questionnaire.
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 randomisation	No randomisation	No randomisation
ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:		
RESEARCH REQUIRES IERC REVIEW	AUDIT DOES NOT REQUIRE IERC REVIEW, unless results are to be published in a scientific journal or disseminated beyond the host institution.	SERVICE EVALUATION DOES NOT REQUIRE IERC REVIEW, unless results are to be published in a scientific journal or disseminated beyond host institution.

Appendix 2: Application to Involve Human Participants in Research

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

Please refer to the Research Committee's Letter of research/grant approval_____(Ref No). If you have questions about this form, please contact the Principal Investigator _____(Full Names) at

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

Email: _____

Date:

SECTION A – GENERAL INFORMATION

1. **Title of the Research Project:** _____

   Key Words:
   _____

   Study Area:

   _____

   (e.g Service delivery (Maternal health, Child health, nutrition, hygiene, sanitation, HiV, non-communicable diseases conditions etc). Medical products, vaccines and technologies. Health systems financing. Leadership and governance. Health information system. Human Resources for Health. Health Infrastructure, equipment. etc**)**

2. **Investigator Information (***Include the PI, Co-PIs and students/Trainees involved***)**

	Name & position	**Dept./Address**	**Phone No.**	**E-Mail**
Principal Investigator				
***Co-Investigator (1)**				

Co-Investigator (2)				
Student (1)				
Student (2)				

*Add rows as necessary

3. **Proposed Date**

a) of commencement:_____ b) of completion:_____

(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*.)

4. **Location/s** where the research will be conducted:_____

5. **Other Research Ethics Committee/Board/IRB Approval**

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

c) 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: _____

	Yes	**No**
d) Will any other Research Ethics Board be asked for approval?	☐	☐

If **Yes**, please specify: _____

6. **Level of the Project**

Faculty ☐
Staff Research ☐
PhD Thesis ☐
Masters Thesis ☐
Undergraduate research ☐
Other (please specify): _____

7. **Funding of the Project**

	Yes	**No**
a) Is this project currently funded?	☐	☐

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

b) Agency or Sponsor (funded or applied for): _____

c) Amount: _____

8. **Conflict of Interest**

a) Will the researcher(s), members of the research team, and/or their partners or immediate family members:
   i) 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** ☐
   ii) 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.)

b) 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).

c) Discuss the possibility of commercialization of the research findings., in any

SECTION B – SUMMARY OF THE PROPOSED RESEARCH

9. **Rationale**

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

Synopsis:

Aims/objectives:

Significance/justification:

Research questions:

10. **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

Subject Selection

Intervention

Methods of Data Analysis

11. **Experience**

What is your experience with this kind of research?

12. **Participants**

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

13. **Recruitment**

a) 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.

b) How and where will you contact these participants?

c) Time required of participants: on occasion(s).

d) Are participants proficient in the language in which the survey is being conducted?
Yes ☐ No ☐

If not, is translation available?

Yes ☐ No ☐

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

14. **Compensation**

a) Will participants receive compensation for participation?

	Yes	**No**
i) Financial	☐	☐
ii) Non-financial	☐	☐

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

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

SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

15. **Possible Risks**

a) Indicate if the participants might experience any of the following risks:

	Yes	**No**
i) Physical risk (including any bodily contact or administration of any substance)?	☐	☐
ii) Psychological risks (including feeling demeaned, embarrassed worried or upset)?	☐	☐
iii) Social risks (including possible loss of status, privacy and/or reputation)?	☐	☐
iv) Is there any deception involved?	☐	☐
v) Are any possible risks to participants greater than those the participants might encounter in their everyday life?	☐	☐

b) If you answered **Yes** to any of points i) through v) above, please explain the risk.

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

16. **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.

SECTION D – THE INFORMED CONSENT PROCESS

17. **The Consent Process**

a) 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.

b) 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

18. **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.

19. **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.

20. **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.

21. **Participant withdrawal**

a) 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.

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

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

SECTION E – CONFIDENTIALITY

22. Ensuring confidentiality

	Yes	**No**
a) Will all participants be anonymous?	☐	☐
b) Will all data be treated as confidential?	☐	☐

(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.)

c) 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.

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

e) 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.

SECTION F – MONITORING ONGOING RESEARCH

23. **Adverse events** (unanticipated negative consequences or results affecting participants) must be reported to the IERC as soon as possible.

24. **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 IERC)

SECTION G – BRIEF CURRICULUM VITAE (All Investigators/ Supervisors/ Students Involved)

(copy this page as required)

Surname: **First name:**

For monitoring purposes only please indicate: Sex: Nationality:

EDUCATION/TRAINING

Institution And Location	Degree	Completion Date	Field Of Study
1.			
2.			
3.			
4.			

Most recent posts held

	Types of posts held	**Institution**	**Period**
1.			
2.			
3.			
4.			

Recent publications: list only <u>five most important and relevant</u> 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]*.

SECTION H – 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 IREC.

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

Appendix 3: Progress Report Form

INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)
THE AGA KHAN UNIVERSITY - KENYA
PROGRESS REPORT

(IERC 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 IERC	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 IERC	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**

8. Has the IERC 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**

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

I confirm that this research project is in conformity with the requirements of sponsor[2] and the approval of the IERC and (and subject to any changes subsequently approved) and that all amendments are already reported to the Research Office.

All financial matters are dealt according to the grants & contracts office guidelines.

Principal Investigator/Primary Supervisor:

Name: _____ Department: _____

Signature: _____ Date:_____

Department Chair:

Name: _____ Department: _____

Signature: _____ Date:_____

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

Appendix 4: IERC Review Evaluation Form

INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)
THE AGA KHAN UNIVERSITY - KENYA
RESEARCH ETHICS REVIEW EVALUATION FORM

Application No: year/IERC- ….

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/IERC/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 concerned 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) ☐ Reject ☐

Appendix 5: Exemption Procedure

INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)
THE AGA KHAN UNIVERSITY - KENYA
PROCEDURE FOR ISSUE OF EXEMPTION LETTER BY IERC FOR SELECTED STUDIES

The studies in which human subjects are not involved directly, or no intervention is done are often exempted from full AKU- IERC review. Since majority of journals ask for approval by an Institutional Review Board or by AKU-IERC before accepting a manuscript for publication, it is necessary that the researchers get an approval or an exemption letter from IERC *before* starting the study, as it is unacceptable for IERC 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 IERC for obtaining a letter of exemption prior to the commencement of the study as IERC 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 IERC 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-IERC on the prescribed form (attached).
   1.4. The proposal along with the DRC's recommendation will be submitted electronically to AKU-IERC secretariat along with one hardcopy.
   1.5. The recommendations will be reviewed by Chair of IERC. If no ethical issue is found, the Chair of IERC will issue a letter of exemption within seven days of receipt of the recommendation.
   1.6. In case Chair of IERC is not satisfied with recommendation, full proposal will be asked for review in the AKU-IERC 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-IERC.

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 (IERC) 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 IERC chair who will decide if the project is exempt or not as per Procedure For Submitting Applications**:** stated in section one above.

Each exempt category is described below. The regulatory text is in blue, and clarifications follow.

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 is 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 IERC conducts a limited IERC 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 IERC review.

2.3. **EXEMPT CATEGORY 3:**

Research involving benign behavioural 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 IERC conducts a limited IERC review.

For the purpose of this provision, benign behavioural 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 behavioural 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 decisionally 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 IERC 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 IERC conducts a limited IERC 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

V. July 17, 2018

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-IERC 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-IERC.

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-IERC with a recommendation for expedited approval. However, in case of faculty and other researchers, such proposals should be submitted to AKU-IERC 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 6: IERC Application Form for Exemption of Studies from Ethical Review

INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)
THE AGA KHAN UNIVERSITY - KENYA
Application Form for Exemption of Studies from Ethical Review

Study Details	Title:
	Key Words:
	Study Area:

2. Principal Investigator	Name	Department

3. Co-PI's	Names	Department

4. Signature of PI	

Please mark the appropriate box as √

5. Types of study		Yes	No
a.	Retrospective review of patient's charts		
b.	Prospective data collection from patient's charts		
c.	Analysis of laboratory/ radiology data		
d.	Clinical audit		

e.	Evaluation of practice guidelines		
f.	Case reports		
g.	Others; please specify		

6. Period of data collection			
From		to	

7. Starting date of study			

8. Summary of data to be collected		Yes	No
a.	Demographics of the patients i.e. name addresses, phone numbers, e-mail address		
b.	Clinical notes		
c.	Photographs		
d.	Laboratory data/ radiology data		
e.	Management data		
f.	Other, please specify		

9. Utilization of data to be collected: Will it be used for		Yes	No
a.	Publication of papers in journals / newspapers		
b.	Oral / poster presentation in meetings / conferences		
c.	Students / residents' teaching		
d.	Planning subsequent larger studies		

10. Summary of Objectives & Methods of Study including selection and exclusion criteria of study subjects, sample size, analysis plan etc.

11. Please answer the following questions and mark the appropriate box as √

		Yes	No
a.	Will any photographs be used/taken for publication?		
b.	If yes, has written permission been obtained from study subject or guardian?		
c.	Has the study been reviewed be departmental research / review committee		
d.	Was any ethical concern raised by departmental committee?		
e.	If yes, what were the ethical issues?		
f.	Were those ethical concerns resolved?		

EDUCATION/TRAINING

Institution And Location	Degree	Completion Date	Field Of Study
1.			
2.			
3.			
4.			

Most recent posts held

	Types of posts held	**Institution**	**Period**
1.			
2.			
3.			
4.			

Recent publications: list only five 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]*.

Certificate of review by the Departmental Research/ Review Committee

and Chair of the Department

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

Name of DRC Chair _____

Signature _____

Date _____

Name Department Chair _____

Signature _____

Date

For IERC

	Yes	**No**	**Signature of Chair IERC**
Exemption granted			
If not, then state the reasons			

Has the PI been informed about decision of IERC?			
If yes, has any response been received?			
If yes, has the response been reviewed by the Chair of IERC?			
If yes what decision was taken? Was exemption granted?			

Appendix 7: Response to Institutional Ethics Review Committee comments

Response to *Institutional Ethics Review Committee* comments

To the Chair, Institutional Ethics Review Committee (IERC)

Study Title:
Author:

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

S. #	IERC 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 8: IERC Team

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

This SoPs were revised and updated in December 2017 by;

Dr Amyn B Lakhani	IERC Chair and Assistant Professor, AKU
Dr Eunice Ndirangu	Academic Head, AKU SONAM, Kenya
Dr. Asad Raja	The Quaid-e-Azam Professor & Chairman Department of Surgery, AKU
Dr. Boniface Mativa	Utilization Management and Clinical Services Quality Director, AKUHN
Dr. Karatu Kiemo	Social Scientist, Nairobi University
Dr. Rodney Adam	RC Chair and Professor, AKU
Dr. Waweru-Siika Wangari	Critical Care Director and Assistant Professor, AKU
Dr. William Macharia	Associate Dean Research and Professor, AKU
Mr. Ambrose Rachier	Chair KEMRI Ethics Committee and Partner Rachier & Amollo Advocates
Mr. James Orwa Kenyatta	Biostatistician, AKU
Mr. Ochieng Rapuro	Managing Editor, Business Daily - Nation Media Group
Ms. Jacqueline Ndegwa	Administrative Assistant, AKU Research Office
Ms. Jaimini Kishore Gohil	Chief Pharmacist, AKUHN
Ms. Kamanda W. Nancy	IERC Secretary and Administrative Manager, AKU Research Office
Ms. Margret Mbuthi	IERC Vice Chair and Consultant Family Wellness Centre
Ms. Mary Mutua	Administrative Assistant, AKUN Research Office
Ms. Tayreez Mushani	Assistant Professor, AKU SONAM, Kenya
Rev. Philip Noel Owuor	Reverend, All Saints Cathedral –Nairobi

Appendix 9: Reference

KEMRI Scientific and Ethics Review Unit Standard Operating Procedures (SERU SOPs) Version 1.0 Dated 27-SEP-2016. Retrieved 14 Oct. 2017 https://www.kemri.org/images/joomlart/documents/Final%20SERU%20SOPs_27%20Sep%202016%20(3).pdf

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