AGA KHAN UNIVERSITY

FACULTY OF HEALTH SCIENCES

RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE AND STANDARD OPERATING PROCEDURES

SEPTEMBER 2011

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Preamble

Inevitably the search for new knowledge, innovation and collaboration raises questions of an ethical nature. Aga Khan University East Africa Faculty of Health Sciences' mission 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.

Policy

Research within the University involving human subjects must be approved by the Aga Khan University East Africa Faculty of Health Sciences Research Ethics Committee (REC). The REC reports to the Aga Khan University, EA Academic Committee through the Chair.

1. Objectives

The objectives of the Research Ethics Committee (REC) are to:

1.1 Protect the mental, social, physical, welfare, rights, dignity and safety of participants of research.

1.2 Facilitate ethical research through efficient and effective review processes.

1.3 Promote ethical standards of human research.

1.4 Review research in accordance with current core values of Ministry of Science and Technology Strategic Plan 2007 – 2012 which promotes respect for human rights as well as those of the Council for International Organizations for Medical Sciences (CIOMS) guidelines.

2. Functions

The REC's functions are to:

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

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

2.3 Prescribe the principles and procedures to govern human research projects including handling of human tissue and/or confidentiality of personal records.

3. Scope of responsibility

3.1 Research proposals involving humans shall be reviewed by the REC where the research involves patients, clients or staff of the following institutions governed by the Aga Khan University:

- PGME
- ANS, Kenya
- ANS, Uganda

This term of reference does not prohibit the institutions from accepting an ethical approval undertaken by another human research ethics committee. However, such an approval will not be sufficient unless endorsed by REC.

3.2 REC definition of research is adopted from the UK definition of Research Assessment Exercise. 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 to not embody original research.

REC 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.

[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.

4. Status of the REC within AKU, EA

4.1 The REC is an advisory committee of the Aga Khan University, EA Academic Committee with responsibility for:

- granting ethical approval;
- withholding ethical approval; and
- withdrawing ethical approval

for research to be carried out within the institutions noted in Section 3.

4.2 The Aga Khan University, EA Academic Committee is responsible for granting the institutional approval for research to be conducted within its institutions giving due consideration to the advice of the REC. (Note: The Academic Committee may not give approval for research to be conducted within the AKU, EA's institutions unless ethical approval has been granted by the REC.) .

4.3 The Academic Committee has delegated to the REC the authority to:

- give approval on behalf of the AKU, EA for the conduct of ethically approved research in the institutions referred to in Section 3 of these Terms of Reference;
- approve amendments on behalf of the AKU, EA to research conducted at those institutions;
- suspend approval on behalf of the AKU, EA for the conduct of research at those institutions;
- withdraw approval on behalf of the AKU, EA for the conduct of research at those institutions.

5. Accountability of the REC

5.1 The REC is accountable to the Academic Committee. All minutes of REC meeting shall be copied to the Chief Academic Officer, upon confirmation.

5.2 The REC shall provide an annual report to the Academic Committee 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.

5.3 The REC may from time to time bring to the attention of the Academic Committee issues of significant concern.

5.4 A copy of all the committee deliberations will be sent directly to the National Council for Science and Technology

6. Composition

6.1 Membership

6.1.1 The composition of the REC shall include a minimum of 7 and a maximum of 11 members, including but not limited to the following:

- a chairperson;
- at least two members who are lay people, one man and one woman, who have no affiliation with the health service, and are not currently involved in medical, scientific, or legal work;
- at least two members who are health research scientists with knowledge of, and current experience in the areas of research that are regularly conducted at AKU, EA
- a member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- at least one member who is a minister of religion, or a person who performs a similar role in the community; and
- at least one member who is a lawyer.
- 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

6.1.2 To ensure that membership shall equip the REC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.

6.1.3 For the purposes of holding a meeting of the REC, a quorum shall exist when a representative of each of the categories designated in the specified paragraph 6.1.1 is present. In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least five 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 REC.

6.1.4 The REC shall be free to consult any person(s) considered by the REC 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.

6.2 Appointment

6.2.1 The Academic Committee shall appoint members of the REC in consultation with Chair of REC.

6.2.2 Prospective members of the REC through open nominations by a search committee will have the mandate to identify suitable candidates where no nominations have been submitted over a reasonable period of time.

6.2.3 Appointments will be on voluntary basis.

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

6.3 Terms of appointment

6.3.1 Members are appointed for a period of two years and may be reappointed at the discretion of the Academic Committee.

The Chairperson and the Vice are appointed for a period of three years and may be reappointed at the discretion of the Academic Council. Administrative Officer (Research) shall be secretary to the committee with no voting power.

6.3.2 Membership shall lapse if a member fails to attend three consecutive meetings of the REC without reasonable excuse or without notifying the Chairperson, unless exceptional circumstances exist. The Chairperson shall notify the member in writing of such lapse of membership and steps shall be taken to fill the vacancy of the lapsed member.

6.3.3 A member may resign from the REC at any time by giving notice in writing to the Chairperson. Upon receipt of such notice, steps shall be taken to fill the vacancy of the former member.

6.3.4 The Academic Committee may terminate the appointment of any member of the REC through the Chief Academic Officer if :

- it is necessary for the proper and effective functioning of the REC;
- the person is not deemed fit and proper to continue serving on REC;
- the person has failed to carry out his/her duties as a REC member.

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

6.4 Conditions of appointment

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

6.4.2 Members are not offered remuneration. However, members shall be reimbursed for legitimate expenses incurred in attending REC meetings or in otherwise carrying out the business of the REC.

6.4.3 Members shall be required to sign a statement undertaking:

- that all matters of which he/she becomes aware during the course of his/her work on the REC shall be kept confidential;
- that any conflicts of interest which exist or may arise during his/her tenure on the REC 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 REC member.

6.5 Education for REC members

6.5.1 Newly appointed members shall be provided with adequate orientation.

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

7. Conduct of business

7.1 Procedures

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

7.2 Submissions, notifications and approvals

7.2.1 All applications for ethical approval must be submitted to the Administrative Officer (Research) office, by the relevant closing date, in writing in the format approved from time to time by the REC and shall include such documentation as the REC may specify.

7.2.2 All submissions to REC shall be through the Research Committee with a confirmation that the proposed work is scientifically sound. Guidelines shall be issued to assist applicants in the preparation of their applications.

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

7.2.4 The REC shall consider every correctly completed application which it receives at its next available meeting following receipt, provided that the application is received by the relevant closing date. The Administrative Officer (Research) shall circulate the completed application and associated documents received with a meeting agenda to all members of the REC at least ten (10) working days prior to the next meeting.

7.2.5 The REC may refer back to the Research Committee certain scientific/technical matters for clarification as necessary. The REC may also obtain expert scientific/technical advice, subject to paragraph 6.1.4 from outside the Research Committee.

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

7.2.7 Following its review, the REC shall promptly notify the applicant through the Chair of Research Ethics Committee in writing with a copy to the Chair of Research

Committee, advising whether the application has received ethical approval and any conditions of that approval. If the REC has granted approval, it shall inform the applicant in writing that the research may commence subject to adherence with laid down guidelines.

7.3 Expedited review

7.3.1 The REC may establish an Executive, consisting of at least the Chairperson (or nominee), Vice Chairperson (or nominee) and Administrative Officer (Research). In accordance with the standard operating procedures, the Executive may undertake expedited review of research proposals between scheduled meetings at the discretion of the Chairperson. The Executive may seek advice from other REC members, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the next REC meeting.

7.3.2 **Expedited Review** is defined as the review of proposed research by the REC Chairperson or a designated voting member or group of voting members rather than the entire REC.

7.3.3 The Executive may consider other items of business that are considered to be of minimal risk to participants such as expected adverse events, protocol reports, minor amendments and the like. The minutes of any such meetings shall be tabled for ratification at the next REC meeting.

7.4 Multi-centre research

7.4.1 To facilitate multi -centre research the REC may:

- communicate with any other REC;
- accept a scientific/technical and/or ethical assessment of the research by another REC upon an expedited review to ensure compliance with institutional guidelines.

7.5 Exportation of samples

7.5.1 When human 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 samples may be justified if there is lack of expertise or equipment. REC may however assess whether any effort is being made to capacitate the "weaker" partner through training 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.

7.5.2 Before applying for exportation of samples, the researcher should ensure that there is a suitable REC at the receiving institution abroad that will take charge of the ethical issue related to the exported samples.

7.5.3 The requests for exportation of the samples will be referred to the National Council for Science and Technology for concurrence.

7.6 Advocates and interpreters

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

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

7.7 Meetings

7.6.1 The REC shall meet on a regular basis, which shall normally be at monthly intervals.

7.6.2 Meeting dates and agenda closing dates shall be published at the beginning of each calendar year.

7.6.3 Any member of the REC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the REC 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 REC'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 minuted.

7.6.4 The REC 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 examined the proposal, provided that the majority includes at least one layperson.

7.8 Records

7.8.1 The Administrative Officer (Research) shall prepare and maintain written records of the REC's activities, including agendas and minutes of all meetings of the REC.

7.8.2 The Administrative Officer (Research) shall prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the REC.

7.8.3 Files shall be kept securely and confidentially in accordance with the acceptable data protection requirements.

7.8.4 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least five years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply. Files which are no longer required for retention shall be electronically archived.

7.8.5 The REC shall maintain a register of all the applications received and reviewed.

8. Post-approval responsibilities

8.1 The REC shall monitor approved projects for compliance with the REC's ethical approval. In doing so, the REC may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the REC shall require investigators to provide interim report, and at completion of the study.

8.2 The REC 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:

- proposed changes in the research protocol or conduct;
- unforeseen events that might affect continued ethical acceptability of the project;
- serious unexpected adverse reactions occurring in participants at sites monitored by the REC and other adverse events as decided by the REC; and

- if the project is abandoned for any reason.

8.3 The REC may adopt any additional appropriate mechanism for monitoring as deemed necessary.

9. Complaints and review

9.1 Complaints concerning the conduct of a project

9.1.1 For proposals that are rejected by REC, the applicant is allowed to appeal if s/he feels that s/he can make a stronger case or has addressed all the objectives of the study. In such a case, the applicant will be allowed to re-submit the proposal. Any concern or complaint about the conduct of a project should be directed to the attention of the person nominated by the REC. The person nominated by the REC to receive complaints shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson of the REC shall investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Academic Committee or its nominee, or request the Chairperson to do so.

9.1.2 Any concern or complaint about the conduct of a project should be directed to the attention of the person nominated by the REC. The person nominated by the REC to receive complaints shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson of the REC shall investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Academic Committee or its nominee, or request the Chairperson to do so.

9.2 Complaints concerning the REC's review process

9.2.1 Any concern or complaint about the REC's review process should be directed to the attention of the Chairperson of the REC, detailing it in writing. Complaints may also be made to the Academic Committee through its Chair. The Chairperson shall notify the Academic Committee of any complaints received by him/her, as soon as possible. The Academic Committee shall inform the Chairperson of any complaints received by the Committee as soon as possible.

The Chairperson shall investigate the complaint and its validity, and make a recommendation to the REC on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Academic Committee, or its nominee,

or request the Chairperson to do so. The Chairperson shall provide to the Academic Committee all relevant information about the complaint/concern. The Academic Committee shall determine whether there is to be a further investigation of the complaint. If it is decided that there is to be a further investigation, then the Academic Committee shall convene a suitable panel to review the complaint, ensuring that both the complainant and the REC are afforded the opportunity to make submissions.

9.2.2 In conducting its review, the panel shall be concerned with ascertaining whether the REC acted in accordance with its Terms of Reference, its Standard Operating Procedures, or otherwise acted in an unfair or biased manner.

9.3 Complaints concerning the REC's rejection of an application

9.3.1 A person with a complaint about the REC's rejection of his/her application should bring the complaint to the attention of the Chairperson of the REC, detailing the grounds of the complaint. Complaints may also be made to the Academic Committee. The Chairperson shall notify the Academic Committee of the complaint as soon as possible. The Academic Committee shall notify the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson shall investigate the complaint and its validity, and make a recommendation to the REC on the appropriate course of action at its next meeting. At the Chairperson's discretion, the complainant may be invited to attend the next REC meeting, or the complainant may request the opportunity to attend.

The complainant shall be informed of the REC's response in writing, normally within seven (7) working days of the REC meeting. If the complainant is not satisfied with the action taken by the REC, then he/she can refer the complaint to the Academic Committee, or its nominee, or request the Chairperson to do so. The Chairperson shall provide to the Academic Committee all relevant information about the complaint. The Academic Committee shall determine whether there is to be a further investigation of the complaint. If it is decided that there is a case to be investigated, then the Academic Committee shall convene a suitable panel to review the complaint, ensuring that both the complainant and the REC are afforded the opportunity to make submissions.

The outcomes of this process may include:

- The complaint/concern is dismissed.

- The complaint/concern is referred back to the REC for consideration, bearing in mind the findings of the panel.

- The application may be referred for external review by an independent REC if the Academic Committee concludes that due process has not been followed by the REC in reaching its decision.

Should the REC be requested to review its decision, then the outcome of this review by the REC shall be final. In accordance with paragraph 4.2, the panel or Academic Committee cannot substitute its approval for the approval of the REC.

10. Review/amendment of terms of reference

10.1 The Executive Committee of the REC shall review the Terms of Reference annually and propose changes to the Academic Committee for approval if appropriate.

10.2 Members of the REC may from time to time propose changes to the Terms of Reference for review by the REC. If considered acceptable, such changes shall be forwarded to the Academic Committee for approval if appropriate.

STANDARD OPERATING PROCEDURES

1.1 Application procedures

a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation
b. All relevant documents should be enclosed with application form
c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the PI to the REC.
d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

1.2 Documentation

For a thorough and complete review, all research proposals should be submitted with the following documents:

a. Name of the applicant with designation
b. Name of the Institute/ Hospital / Field area where research will be conducted.
c. Approval of the Head of the Department / Institution
d. Protocol of the proposed research
e. Ethical issues in the study and plans to address these issues.
f. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.
g. Informed consent process, including patient information sheet and informed consent form in local language(s).
h. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
i. Curriculum vitae of all the investigators with relevant publications in last five years.
j. Any regulatory clearances required.
k. Source of funding and financial requirements for the project.
l. Other financial issues including those related to insurance
m. An agreement to report only Serious Adverse Events (SAE) to REC.
n. Statement of conflicts of interest, if any.
o. Agreement to comply with the relevant national and applicable international guidelines.
p. 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 RECs 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.

q. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
r. Any other information relevant to the study

1.3 Review Procedures

a. The meeting of the REC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.
b. The proposals will be sent to members at least ten (10) working days prior to the next meeting.
c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
d. Researchers will be invited to offer clarifications if need be.
e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
f. The decisions will be minuted and Chairperson's approval taken in writing.

1.4 Element of review

a. Scientific design and conduct of the study.
b. Approval of Research Committee.
c. Examination of predictable risks/harms.
d. Examination of potential benefits.
e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other relevant issues.
f. Management of research related injuries, adverse events.
g. Compensation provisions.
h. Justification for placebo in control arm, if any.
i. Availability of products after the study, if applicable.
j. Patient information sheet and informed consent form in local language, where relevant.
k. Protection of privacy and confidentiality.
l. Involvement of the community, wherever necessary.
m. Plans for data analysis and reporting
n. Adherence to all regulatory requirements and applicable guidelines
o. Competence of investigators, research and supporting staff (CVs)
p. Facilities and infrastructure of study sites
q. Criteria for withdrawal of patients, suspending or terminating the study

1.5 Follow up procedures

a. Reports should be submitted at prescribed intervals for review.
b. Final report should be submitted at the end of study.
c. All Serious Adverse Events and the interventions undertaken should be intimated.

d. Protocol deviation, if any, should be informed with adequate justifications.
e. Any amendment to the protocol should be resubmitted for renewed approval.
f. Any new information related to the study should be communicated.
g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
h. Change of investigators / sites should be informed.

1.6 Record keeping and archiving

a. Curriculum Vitae (CV) of all members of REC.
b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
c. Minutes of all meetings duly signed by the Chairperson.
d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
e. Copy of all correspondence with members, researchers and other regulatory bodies.
f. Final report of the approved projects.
g. All documents should be archived for prescribed period.

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

Research	Clinical audit	Service evaluation
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies, explores themes following established methodology.	Designed to answer the question: "Does this service reach a predetermined standard?"	Designed to answer the question: "What standard does this service achieve?"
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research - may involve evaluating or comparing interventions, particularly new ones. Qualitative research - usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
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 REC REVIEW	**AUDIT DOES NOT REQUIRE REC REVIEW, unless results are to be published.**	**SERVICE EVALUATION DOES NOT REQUIRE REC REVIEW, unless results are to be published.**

Annex 2: Application to Involve Human Participants in Research Aga Khan University East Africa

Research Ethics Committee (REC)

Application to Involve Human Participants in Research

Please refer to the AKU EA 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:** _____

_____

2. **Investigator Information**

	Name & position	**Dept./Address**	**Phone No.**	**E-Mail**
Principal Investigator				
***Co-Investigator(1)**				
Co-Investigator (2)				
Co-Investigator (3)				

*Add more Co-Investigators 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** where the research will be conducted:_____

5. **Other Research Ethics Board Approval**

Yes No

a) Is this a multi-centred study? ☐☐
b) Has any other institutional Ethics 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: __/___/_____

A copy of the clearance certificate / approval: See attached

Yes No

d) Will any other Research Ethics Board be asked for approval? ☐☐
If **Yes**, please specify: _____

(See attached approval/grant letter)

6. **Level of the Project**

Faculty/Staff Research ☐

PhD Thesis ☐

MastersThesis ☐

Other (please specify):

7. **Funding of the Project**

Yes No

a) Is this project currently funded? ☐☐
b) Period of Funding: _____ To:

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

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.

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:

Significance:

Research questions:

10. **Methodology**

Your proposal which will be reviewed should describe sequentially, and in detail, all procedures in which the research participants will be involved (e.g., interviews, surveys, questionnaires, physical assessments, physiological tests, time requirements etc.)

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

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).

Yes No

d) Are participants proficient in the language in which the survey is being conducted? ☐☐
If not, is translation available? ☐☐

14. **Compensation**

a) Will participants receive compensation for participation? **Yes No**
i) Financial ☐☐
ii) Non-financial ☐☐

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

c) 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 Letter of Information (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 REC 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 REC)

SECTION G – SIGNATURES

Principal Investigator Assurance:

As a Principal Investigator, 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 Research Committee.

Signature of Principal Investigator **Date**

Annex 3: Progress Report Form

AGA KHAN UNIVERSITY

RESEARCH ETHICS COMMITTEE

PROGRESS REPORT

R E S E A R C H P R O J E C T S

PROJECT ID _____ _____

FROM AND **TO**

PROJECT TITLE :

_____

_____

PRINCIPAL INVESTIGATOR

_____

_____

[2]**PLEASE COMPLETE AND RETURN THIS FORM NO LATER THAN:**

1. PROJECT COMMENCEMENT DATE: _____

2. 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

3. IS THE PROJECT COMPLETE ? YES IF, YES, GIVE DATE ☐

NO ☐

4. THIS REPORT COVERS THE PERIOD BETWEEN _____ TO _____

[2] Submit Progress Report to Administrative Officer (Research)

5. HAS THE PROJECT BEEN CONDUCTED IN ACCORDANCE WITH THE PROTOCOL APPROVED BY THE REC?

☐ Yes ☐ No

IF NO, PLEASE GIVE DETAILS.

6. HAVE YOU MADE ANY MAJOR MODIFICATION IN THE ORIGINAL PROTOCOL OR METHODOLOGY, OR WORK PLAN?

☐ Yes ☐ No

IF YES, PLEASE DETAIL REASONS FOR MODIFICATIONS. (ATTACH A SEPARATE SHEET)

PLEASE REMEMBER THAT ANY AMENDMENTS TO THE APPROVED PROTOCOL REQUIRE FURTHER SPECIFIC APPROVAL BY REC.

I CONFIRM THAT THIS RESEARCH PROJECT IS IN CONFORMITY WITH THE SPONSOR[3] AND THE APPROVAL OF THE ETHICAL REVIEW COMMITTEE AND (AND SUBJECT TO ANY CHANGES SUBSEQUENTLY APPROVED) AND THAT ALL MAJOR AMENDMENTS ARE ALREADY REPORTED TO THE RESEARCH OFFICE.

Principal Investigator

Name	**Department**

Annex 5: Ethical Requirements of Clinical Research

SIX ETHICAL REQUIREMENTS OF CLINICAL RESEARCH

REC will base its evaluation of the submitted proposals on the following six ethical criteria.

1. Social or scientific value:

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

2. Scientific validity:

- Methods must be valid
- Clear scientific objective
- Use of accepted principles/reliable practices
- Have sufficient power to test the objective (no biased sample)
- Offer plausible data analysis plan
- Proposed plan must be executable

3. Fair subject selection:

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

- Selection of subjects must be fair
    - Inclusion/exclusion criteria of who are/and who are not to be in the study
    - Clear strategies of recruitment be adopted
- Fair subject selection requirements
    - Scientific goals of the study, not vulnerability or privilege, be 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

4. Favourable Risk-Benefit ratio:

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 such research to be justifiable:

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

5. Informed consent (I/C):

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

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 voluntary and uncoerced decision whether to participate

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.

6. Respect for potential and enrolled subjects:

- Respect for study participants is justified by several principles
    - Beneficence (prevent, remove evil/harm and promote good)
    - Nonmaleficence (do not inflict harm/evil)
    - Respect for persons
- Protecting confidentiality and monitoring well being are motivated by
    - Respect for persons
    - Beneficence
    - Nonmaleficence

Universality of the requirements

The 6 requirements for ethical clinical 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.

Annex 6: REC Review Evaluation Form

AKU, EA FACULTY OF HEALTH SCIENCES
RESEARCH ETHICS REVIEW EVALUATION FORM

Application No: year/REC- ….

Title:

		Yes	No	N/A	Comments
	Is all the documentation provided?				
	Scientific importance and validity				
1	Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2	If the study is a replication of a previous study, is it justified?				
3	Can the intervention studied be practically implemented?				
4	Is there provision for dissemination of results of the research?				
5	Has the research protocol been approved by a competent body?				
6	Should the study be referred to a technical expert, po.licy maker or statistical expert?				
	If YES, please inform the Administrative Officer (Research) as soon as possible, suggesting a suitable person.				
7	If NOT, Are the objectives stated clearly?				
8	Is the study design appropriate in relation to the objectives?				
9	Is the study designed using accepted principles, methods and practices?				
10	Is there a plausible data analysis plan?				
11	Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of research participants?				
12	Are the investigators qualifications, competence and experience appropriate to				

		Yes	No	N/A	Comments
	conduct the study?				
13	Are the facilities at the site adequate to support the study?				
14	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	Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
3	Is it safe to use the intervention in the research?				
4	Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
5	Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
6	Is the standard of care the best available locally?				
7	Is the medical and psychological support for the participants adequate?				
8	Is the site including support staff, facilities and emergency procedures adequate?				
9	Is there provision for compensation for participants who sustain injuries?				
10	Have adequate provisions been made for dealing with and reporting adverse effects?				
11	Have adequate provisions been made for safety monitoring and termination of the research project?				
13	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	Are the participants competent?				

		Yes	No	N/A	Comments
3	Is the justification for the intention to include individuals who cannot consent adequate?				
4	Are the arrangements for obtaining proxy consent for such individuals appropriate?				
5	Will dissent be respected?				
6	Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
7	Do you approve the incentives offered?				
8	Is the consent given voluntarily and not due to deception, intimidation or inducement?				
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	Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				
2	Is the privacy of the research participant safeguarded?				
3	Are data/sample storage and disposal procedures adequate?				
	Rights of the participants				
1	Is the participant's right to unconditionally withdraw from the research at anytime 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 clinical 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				

		Yes	No	N/A	Comments
	study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
2	Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
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?				
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	Is the medical care to be provided to the research participants during and after the research adequate?				
2	Has the researcher followed any applicable legal regulations or other guidelines?				
3	Has the researcher obtained permission from the relevant authorities?				
4	Are there any conflicts of interest, including payments and other rewards?				
5	Are there any other ethical / legal/ social /financial issues in the study?				
	Vulnerable group				
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) consent adequate?				
4	Will the subject's withdrawal from research due to refusal (dissent) be always upheld?				
5	Is there a favourable risk benefit ratio?				

		Yes	No	N/A	Comments
6	Is the medical and psychological support adequate?				
7	Will the benefit of the research be made reasonably available to this group?				
	Externally sponsored research				
1	Is there a local collaborator?				
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 AKU, EA and not in the sponsoring country/institution adequate?				
4	Is the research relevant to AKU, EA/Kenya?				
5	Are the post-research benefits to AKU, EA/Kenya acceptable?				
6	Are relevant local laws/ regulations/ guidelines of each country adhered to?				
7	Is the research responsive to cultural/social differences?				
8	Are participants receiving the best current treatment as part of the protocol?				
9	Is the ancillary care provided adequate?				
10	Are the provisions for continuity of care adequate?				
11	Are the provisions for intellectual property sharing fair?				
12	If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights?				
13	Is there provision for results of research to be conveyed to relevant authorities in AKU, EA?				
14	Are any conflicts of interest resolved?				
15	Is there a written agreement between the collaborators?				

		Yes	No	N/A	Comments
	Community based research				
1	Is the impact and relevance of the research on the community in which it is to be carried out acceptable?				
2	Has the concerned community been consulted during the design of the study?				
3	Is community consent obtained?				
4	Is individual consent obtained?				
5	Is the privacy of the participants safeguarded?				
6	If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?				
7	Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?				
8	Does the research contribute to capacity building of the community?				
9	Will the results of the research be made available to the concerned community?				
10	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 teratogenecity trials been carried out?				
4	Is their sufficient justification for using a 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?				

Additional comments

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Recommendation: Approve / Reject / Resubmit (please state the conditions)

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Name of Reviewer:……..

Signature: ……..

Date:……/……/…….