**Ethics Review Committee**

**Terms of Reference**

**1.0 Preamble**

The Ethics Review Committee (ERC) shall be concerned with ethical issues involved in proposals for research on human subjects. The terms of reference have taken into consideration recommendations of a sub-committee of the Bio-ethics Group of Faculty of Health Sciences (FHS) and particularly the report of the Royal College of Physicians of London (1996) titled "Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects". The terms have been derived mainly from principles and generalised for application to both bio-medical and social science research. A deliberate attempt has been made to avoid detail, with the expectation that experience will determine the need for revision and elaboration.

**2.0 Terms of Reference​**

2.1 All research projects involving human subjects, whether as individuals or communities, including the use of foetal material, embryos and tissues from the recently dead, undertaken or supported by Aga Khan University (AKU) faculty, staff or students, wherever conducted, shall be reviewed by the ERC before a study can begin.

2.2 The duration of approval for a study shall be limited. Any change in conditions that could affect the rights of subjects during a study must be approved for the study to continue.

2.3 The Committee shall provide written guidelines on ethical considerations for research involving humans and review them at least once in two years. The guidelines shall be based on but not restricted to the following principles:

* Respect for an individual's capacity to make reasoned decisions, and protection of those whose capacity is impaired or who are in some way dependent or vulnerable.
* The risks of the proposed research in respect of expected benefits, the research design and competence of the investigators having been assessed.
* A proposal must state the purpose of the research; the reasons for using humans as the subjects; the nature and degree of all known risks to the subjects; and the means for ensuring that the subjects' consent will be adequately informed and voluntary.
* The subjects of research should be clearly aware of the nature of the research and their position in respect of it.
* Consent must be valid. The participants must be sufficiently informed and have adequate time to decide without pressure. Consent must be obtained from the subjects, preferably written.
* Subjects must be able to easily withdraw from a research protocol without giving reasons and without incurring any penalty or alteration in their relationship with providers of services.
* Further guidance should be obtained from publications, such as the World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (1989), consultation with experts and other sources, according to need.
* Specify procedures, including periodic appraisal of the progress of approved projects, for ensuring that subjects of research are protected from harm, their confidentiality is maintained, and their rights are respected.

2.4 The Committee shall report annually or more frequently, as necessary, to the URC and the Chief Academic Officer.

2.5 **Method of Working**

2.5.1 The Committee will need substantial administrative and secretarial assistance from the Research Office.

2.5.2 Authors of research proposals may be invited to attend meetings of the ERC when their study is being reviewed.

2.5.3 Some business may be conducted by mail, but reasonably frequent meetings are essential to allow a committee ethos to develop.

2.5.4 A quorum should include a layperson, a research oriented member who is broadly familiar with the proposed field of study, and a member of each gender.

2.5.5 Decisions will be made normally by consensus.

2.5.6 The Chairman's approval may be given for studies that pose no ethical problems. Such approvals shall be reported to the next meeting of ERC for ratification.

2.5.7 Investigators are entitled to have an adverse decision reviewed, and to make written and/or oral representations to the Committee.

2.5.8 The Committee may withdraw approval if it is not satisfied with the conduct of the investigation.

2.5.9 The ERC should approve amendments to protocols that affect human subjects.

2.5.10 Confidentiality of the Committee's proceedings should be preserved.

2.5.11 Members of the Committee should declare their own interests, for example when testing of the product of a company of which the member is an advisor.

2.5.12 Serious adverse events should be reported promptly to the Chair.

2.5.13 Members should not be paid; however, if honorarium is necessary, then it should be modest.

2.6 **Membership**

2.6.1 Membership shall include representation from researchers, the professional disciplines currently found in the University, discerning public, legal expertise, and both genders.

2.6.2 The Chief Academic Officer shall appoint the chair and members, in consultation with the URC.

2.6.3 The tenure of AKU members on ERC shall be 3 years which may be renewed for one term.

2.6.4 The tenure of External Members on ERC would be of one year which may be renewed for another term of one year at the discretion of the Chair ERC based on the attendance and quality of input by the member. Further extension would require URC's approval.

2.6.5 For faculty, it is essential to select persons who are not members of other research related committees.

2.6.6 The total number of members should not exceed 15, including the chair. In addition, there will be one adjunct member from AKU-East Africa and one from ISMC who would be called upon as required by the Chair to give input for projects falling into their respective areas of expertise.​