



## THE AGA KHAN UNIVERSITY

Policy No. AKU-K/ORGS/008-2022 <b>POLICY ON RESEARCH ETHICS REVIEW</b>	
<i>Contact Office:</i>	Grants Support Office
<i>Approving Authority:</i>	University Research Council
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### 1. RESEARCH ETHICS REVIEW POLICY

#### 1.1. Aim & Purpose of the Policy

This policy sets out the requirements for ethics approval across the Aga Khan University. This policy forms part of a suite 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.

Provided below is a list of policies related to research at AKU and is accessible at:

<https://www.aku.edu/research/policies/Pages/home.aspx>

- 1.1.1. [Authorship Policy](#)
- 1.1.2. [Intellectual Property Rights Policy](#)
- 1.1.3. [Policy on Research Misconduct](#)
- 1.1.4. Policy on [Code of Good Research Practice and Access to Participants Data](#)

Additionally, and more significantly the **National Regulatory requirements** for ethics must be complied with in accordance with the disciplinary and country contexts.

The term Ethics Review Committee is used to refer to the Institutional Scientific and Ethics Review Committee in the Kenyan Context

#### 1.2. Ethics Review Requirements

The policy requires that all research involving humans, whether as individuals or communities, including the use of fetal material, embryos and tissues from the recently dead require ethical clearance in line with the guidelines are set out below.

#### 1.3. Ethical Review Pathways

- 1.3.1. Full Review
- 1.3.2. Ratification of approval from another institution, such as in the case of research in multi-country collaborative research projects
- 1.3.3. Expedited review
- 1.3.4. Time sensitive reviews
- 1.3.5. Exemption from review

## **2. PRINCIPLES GOVERNING THE POLICY**

In addition to the principles of responsible research (e.g. in policies listed in section 2.1), the following principles govern the policy on research involving humans.

### **2.1. No or Minimum Harm**

Every research project involving human participants should assess carefully possible risks and potential harm as compared to foreseeable benefits to the participating individuals or to the society. It is expected that the researcher will ensure no or minimal harm to the participants. By harm is meant any negative impact on the participants as result of their participation in the study.

### **2.2. Voluntary and Informed Consent**

Voluntary consent entails that research participants must be able to take part in research of their own volition without any constraint. Refusal to participate or withdrawal from the study will not result in any penalty or loss of benefits that the participant is otherwise entitled to receive.

Informed consent requires that prior to seeking their consent, research participants should be informed about the key elements of the research as listed below, and what it means for them to take part in it.

#### **2.2.1. Implied Consent**

In some cases, a separate informed consent process may not be required as participants' consent is implicit in their actions.

#### **2.2.2. Substantive limitations**

In certain cases, a full disclosure about the objectives of the study might compromise the study, or might not be possible for other reasons. For example, by law, corporal punishment is banned in most education systems globally but there is circumstantial evidence to show that it is widely prevalent in schools at least in many countries where AKU operates. Informed consent about the objectives of a study on say, 'impact of corporal punishment on the emotional and psychological well-being of students' will not be possible because this practice is illegal and not likely to be owned. Likewise, in an emergency medical situation it might not be possible to go through an information giving stage in seeking consent. In such cases the researcher will not be able to provide information to the participants about the objectives of the study.

Research in journalism often involves interviewing individuals in a position of power (e.g., prime ministers, presidents) who are in a position to give or withhold consent. In such situations a formal process of informed consent may not be always possible or required.

If exemption to informed consent is being asked for, a detailed explanation must be provided to the ethics review committee including a description of the research setting to explain what are the benefits that outweigh the inability to provide information.

### **2.3. Confidentiality and Anonymity**

2.3.1. Confidentiality in research entails that information and records/data shared with the researcher by the research participant in a relationship of trust must not be disclosed to others in ways that are not already agreed upon. Confidentiality measures also require that information and data/records are securely kept and protected from inappropriate disclosure. In the informed consent information must be provided on how confidentiality will be maintained and indicate who will have access to information (e.g., student's supervisor, research team). Researcher must describe the extent to which and how confidentiality of data and records will be maintained.

2.3.2. Researchers must provide anonymity to the participants by collecting data that is not linked to personal identification. Where this approach is not feasible or desirable researchers must take stringent steps to anonymize the data as soon as possible.

- 2.3.3. In case of research in certain disciplinary areas or certain methodological traditions provision of anonymity might not be possible. For example, in journalism, it might not be possible or required to hide the identity of interviews of persons in prominent or powerful positions such as prime ministers or sports-stars. Likewise, certain research methodologies by their very nature make it almost impossible to provide complete anonymity. For example, action research studies in which researchers and practitioners play dual roles and work in multiple teams it is not possible to provide anonymity. In such cases researchers must provide an explanation in their application about why the clause of ‘anonymity’ is not applicable.

## 2.4. Reciprocity

- 2.4.1. Reciprocity in research entails that researchers must actively consider how best to create a balance in what the research participants give and what they get from the research. Reciprocity must not be seen as an afterthought rather it should be woven into the very fabric of the research project, and build on reciprocal relationship between the researcher and the participant.
- 2.4.2. Researchers must make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity.
- 2.4.3. The researcher should consider a variety of ways through which the research participants could be compensated for their time and information. (E.g., offer a summary of the research results, acknowledgment, conduct a workshop or a seminar for schools).

## 3. ETHICS REVIEW SYSTEM

A multi-tiered ethics review system (Appendix ‘A’) is introduced to ensure rigour, efficiency, and relevance to the geographical and disciplinary context. The new system became effective on August 1, 2018.

### 3.1. Ethics Review Board

The Ethic Review Board (ERB) is an AKU wide body responsible for monitoring of ethical compliance in research, policy-making, governance, standardization and oversight of the ethics review process across AKU. The ERB reports to the University Research Council (URC) and submits annual report to the URC. The ERB will work closely with the Ethics Review Committees (ERCs) to ensure the ethical conduct of research. To ensure quality and due diligence in the review process, the ERB reserves the right to review a random selection of applications approved by the ERCs. All the ERCs report to the ERB through their respective chairs.

### 3.2. Terms of Reference – Ethics Review Board

The ambit of the ERB is as laid out in section 3.1 above.

#### 3.2.1. Setting up the ERB

Chair, University Research Council in consultation with the Provost will appoint the chair of the ERB. The chair ERB in consultation with the chair URC will appoint members of the ERB.

- 3.2.2. **Membership:** The ERB will comprise a maximum of 18 members. Tenure of membership would be two years for the chair and internal members, and one year for external members. Membership could be renewed for one more term at the URC chair’s discretion. The Chair’s tenure can be renewed for one more term at the Provost’s discretion.

*Note:* the invitees would not participate in the decision making.

- A Chair
- At least 4 members with expertise and substantial experience in areas of research being undertaken at AKU;
- Chairs of all the AKU Ethics Review Committees.
- Chair may use his/her discretion to invite a specialist for his/her expert advice on a particular matter. However, the invitees would not participate in the decision making.

**3.2.3. Functioning of the ERB:** The ERB is autonomous in its functioning and decision-making. It will create and oversee systems to ensure rigour and transparency in the ethical review and decision making process throughout the university.

**3.2.5. Frequency of meetings:** The ERB will meet three times in a year with a provision for at least one additional meeting in case of need.

**3.2.6. Quorum:** The ERB will be considered quorate with 50% attendance

### 3.3. Ethics Review Committees

**3.3.1.** The Ethics Review Committees (ERCs) at AKU ensures to adherence to the policy and principles of ethics review as noted in the preceding sections. ERCs are responsible to provide rigorous, relevant and timely review of the applications received.

**3.3.2.** The ERCs will work closely with the Ethics Review Board and shall report to it on a quarterly basis. However, they will be entitled to make decisions on the ethical review applications and all related issues directly without prior ratification of the ERB. The ERB reserves the right to review and audit the functioning of individual ERC as outlined in section 3.2.

### 3.4. Terms of Reference – Ethics Review Committees

The ambit of the ERC is as laid out in section 3.3 above.

#### 3.4.1. Setting up the ERC

Chair of the ERC will be appointed by the Associate Dean - Research, who will seek nominations from the relevant Deans and Directors of academic units and also consult the Chair ERB and the Chair URC.

#### 3.4.2. Membership and composition of the ERC

The ISERCs shall comprise of 7-15 members. In the case of ERC for Social Sciences, Humanities and the Arts which is a global committee, the number could be higher (maximum: 15).

- A Chair
- A lay person(s) with no direct affiliation with the University and not engaged in scientific work;
- A legal representative who is an advocate of the high court of Kenya
- A religious representative
- At least two people with current research experience relevant to research proposals being considered by the specific ERC.
- The Chair may use his/her discretion to invite a specialist for his/her expert advice on a particular matter. However, the invitees would not participate in the decision making.

- 3.4.3. Tenure of membership would be two years for internal members and external members. The chair's term will last three years. Membership could be renewed at the chair's discretion or as maybe appropriate. The chair's tenure could also be renewed for one more term at the discretion of the Associate Dean - Research
- 3.4.4. Functioning of ERC: ERCs will ensure transparency in their decision-making. Confidentiality of information shared would be maintained by the members.
- 3.4.5. Frequency of meetings: ERC would meet at least once every month with the provision of an additional meeting if required. A calendar of meeting would be developed and placed on the relevant page on AKU website.
- 3.4.6. Quorum: The ERB will be considered quorate with 50% attendance. However, additional conditions may be applicable in line with the country requirements.

## 4. GUIDELINES AND PROCEDURES

- 4.1. Guidelines and procedures for ethics review of applications are available with respective ERC Secretariat (<https://www.aku.edu/research/urc/erc/Pages/home.aspx>). The guidelines are consistent with the policy as outlined above, and also take account of international standards (e.g., the [Common Rule framework https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects](https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects)), and relevance to the disciplines and country-specific requirements.

### 4.2. Appeals against decisions of ERC:

- 4.2.1. Where principal investigators do not receive ethics approval or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to request a reconsideration of the decision by the ERC.
- 4.2.2. If the request for reconsideration is not successful, they may appeal to the Ethics Review Board a body appointed by the University Research Council (URC). The ERB shall appoint an appeal committee that reflects a range of expertise and knowledge similar to that of the ERC.

#### 4.2.2.1. Grounds of appeal to ERB

- 4.2.2.1.1. If the investigator feels that relevant processes or SOPs were not followed by ERC in arriving at its decision
- 4.2.2.1.2. If the decision of ERC includes administrative measures pertaining to investigators that should be carried out by University authorities (ERC-SOPs need to outline the kinds of decisions ERCs can make, and these should mostly focus on study protocol content rather than on the investigators, as long as investigators are qualified to carry out the proposed work).
- 4.2.3 A complaint may be levied against the ISERC in the following ways.
- 4.2.3.1 Complaints relating to the administrative matter of the ISERC will be channeled to the ERB. This is when the dispute levied is against the functioning of the ISERC. An appeal committee may be set up by the ERB to handle the dispute as in clause 4.2.4 – 4.2.7 below.
- 4.2.3.2 Complaints relating to the technical contents of the protocol under review, Material transfer disputes, data transfer disputes and involvement of research participants in the study will be handled by the ERC. A special meeting of the ERC will be set-up to deliberate and review the dispute as may be necessary. Other relevant organs of the university may be engaged when necessary.
- 4.2.4. The ERB appeal committee may be an ad hoc committee, comprising of 7 members. Criteria for appointment will be developed by ERB, and the committee shall regulate its own procedures. Members of the ERC whose decision is under appeal shall not serve on that appeal committee.

- 4.2.5. The appeal committee shall review the case independently and in detail.
- 4.2.6. The decision of the appeal committee shall be final
- 4.2.7. It should be stressed that the appeal process is not a substitute for ERCs and researchers working closely together to ensure high quality ethical research, nor is it a forum to merely seek a second opinion.

#### **4.3. Complaints about non-compliance of ethics**

- 4.3.4. In case a complaint is received in AKU about non-compliance of approved Ethics Protocols for a study, the complaint should be submitted by the recipient to the chair of the relevant ERC.
- 4.3.5. The chair ERC shall conduct preliminary information-gathering and fact-finding to determine whether the complaint has merit.
- 4.3.6. In case the preliminary information gathering suggests the need for an investigation, the ERC Chair shall make an initial ruling on the event. If the chair decides to suspend the study, then the suspension decision must be ratified in the next ERC full committee meeting. Reasons for suspension must be communicated to the PI or designee in writing and to the relevant research body in AKU namely the Chair ERB with a copy to URC.
- 4.3.7. The PI or designee have the right to appeal the decision against the complaint. The appeal should be on the grounds identified in point No 4.2.2
- 4.3.8. They may appeal to the Ethics Review Board.
- 4.3.9. The ERB shall appoint an appeal committee as described in 4.2 above.
- 4.3.10. The appeal committee shall review the case independently in detail.
- 4.3.11. The decision of the appeal committee shall be final

#### **Reference:**

1. University of Cambridge Research Ethics Review Appeals Procedure: [https://www.research-integrity.admin.cam.ac.uk/files/ethics\\_review\\_appeals\\_procedure.pdf](https://www.research-integrity.admin.cam.ac.uk/files/ethics_review_appeals_procedure.pdf)
2. Reconsideration and appeals: Chapter 6: Governance of Research Ethics Review (Govt. of Canada): [https://ethics.gc.ca/eng/tcps2-eptc2\\_2018\\_chapter6-chapitre6.html#c](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#c)

Appendix

Tiered System

