



THE AGA KHAN UNIVERSITY

Research Policy

<i>Policy No.</i> ORGS/008-2018 POLICY ON RESEARCH ETHICS REVIEW	
<i>Contact Office:</i>	Office of Research & Graduate Studies
<i>Approving Authority:</i>	University Research Council
<i>Endorsed by:</i>	Academic Council
<i>Approved:</i>	March 29, 2018

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>

- [Authorship Policy](#)
- [Intellectual Property Rights Policy](#)
- [Policy on Research Misconduct](#)
- [Code of Good Research Practice](#)

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

1.2. Ethics Review Requirements

The policy requires that all research involving humans, whether as individuals or communities, including the use of foetal 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 anonymise 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 policy-making, governance, 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. The ERB has devolved the power to approve ethics clearance to Ethics Review Committees (ERCs) created as sub-committees of the ERB. 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. The composition of the ERB is as follows:

- 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
- Up to two external members with no affiliation with AKU;
- 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.

3.2.4. **Appeals Process:** Investigators have the right to appeal to the ERB against a decision of ERC. The Chair of the ERB is responsible for timely decision on such appeals in consultation with the ERB members.

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 are sub-committee of 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 Chair ERB in consultation with the Chair URC who will seek nominations from the relevant Deans and Directors of academic units.

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

The ERCs shall comprise of 6-10 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;
- At least two people with current research experience relevant to research proposals being considered by the specific ERC.
- 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 the chair, and one year for external members. Membership could be renewed for one more term at the chair's discretion. The chair's tenure could also be renewed for one more term at the discretion of the Chair ERB.

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>), and relevance to the disciplines and country-specific requirements.

APPENDIX – ‘A’

Multi-tiered ethics review system

