



THE AGA KHAN UNIVERSITY

Ethics Review Committee - Social Sciences, Humanities and Arts (ERC-SSHA)

Terms of Reference (ToR)

1. PREAMBLE

The Aga Khan University (AKU) has seen significant expansion geographically and in academic activities with new campuses and programmes now in at least six different countries. With the geographical expanse of AKU, ethics review processes must comply with the regulatory conditions that govern research in different countries.

Due to the expansion in research activities, especially in the Faculty of Health Sciences (FHS) Pakistan, the ERC was overloaded with applications, which affected the efficiency of the review process. To enhance the efficiency of the ethics review process at AKU and align the ethics review system along with policies and procedures across the University, different ethics review committees at AKU undertook a restructuring of their respective ethical review process.

2. PURPOSE

Previously, one ERC reviewed applications from all disciplines, including FHS and Social Sciences, and Humanities. Researchers and faculty observed that research applications for ethics clearance from the social sciences and humanities required different forms of assessment for their reviews, and therefore, these applications require a separate, suitable ethics review process. In December 2017, the URC approved the restructuring of the ethics committees across all campuses; the **ERC-SSHA** is the body that will assess research applications in the social sciences and humanities.

ERC-SSHA covers all research in the social sciences and the humanities. It is not intended as a review committee for all qualitative research and it does not cover applications in the health sciences. For instance, it would cover applications in medical anthropology and social psychology, but not psychiatry.

3. TERMS OF REFERENCE – ERC-SSHA

3.1 ERC-SSHA is a global committee for research in the Social Sciences Humanities and the Arts, and will accept applications from the following institutes:

- a) Faculty of Arts and Sciences (FAS)
- b) Graduate School of Media & Communications (GSMC)
- c) Institute for Educational Development (IED) (East Africa and Pakistan)
- d) Institute for Human Development (IHD)
- e) Institute for the Study of Muslim Civilisation (ISMC)

- 3.2 This committee cuts across the different campuses of AKU, in the different countries in which the University operates, and is a global committee. The committee will operate in the UK, Pakistan, and Kenya and is envisaged to include Tanzania, Uganda and Afghanistan
- 3.3 There will be a separate secretariat to receive applications.
- 3.4 The committee will develop a uniform system to ensure transparency in the ethical review and decision-making process throughout the University.
- 3.5 The committee will implement standardised nomenclature, policies and procedures, as well as application forms across the different campuses.
- 3.6 A pool of reviewers comprised of committee members past and present will review all research proposals in the social sciences, humanities, and arts, submitted by the faculty of the Institutes listed in 3.1, as well as the Faculty of Arts and Science. The committee's remit is not intended to cover research in the health sciences.

4. MEMBERSHIP AND QUORUM

The committee will follow AKU-ERC guidelines and policy.

- 4.1 *Members:* The ERCs shall comprise 6-10 members, reflect a diversity in membership selection with a balance of geographical location, gender, and disciplines, and will include:
 - a) A Chair
 - b) A Vice-Chair
 - c) Lay person(s) with no direct affiliation with the University and not engaged in scientific work, and not constituting more than 20% of the ERC membership
- 4.2 *Invited members:* The Chair may use his/her discretion to invite a specialist for their expert advice on a particular matter. Invited members will be confirmed by the Chair upon review of their biographical sketch. Invitees will not participate in decision making.
- 4.3 *Tenure of membership:* Three years for internal members and the chair, and one year for external members. Membership can be renewed for one more term at the Chair's discretion. The Chair's tenure can also be renewed for one additional term, at the discretion of the Chair, ERB.
- 4.4 *Quorum:* The ERC-SSHA will be considered quorate with 50% attendance.
- 4.5 *ERC membership criteria and appointment:*
 - a) ERC Chair, Vice-Chair, and members will be full time employees/Faculty at Aga Khan University
 - b) Lay person(s) with no direct affiliation with the University and not actively engaged in scientific work. These can be senior/retired/emeritus professors and should not constitute more than 20% of ERC membership
 - c) Taken together, the committee should possess collective expertise in the fields or disciplines believed to be required for its work.

- d) ERC members should have an understanding of the importance of research and how it can benefit human knowledge production. Members should provide an appropriate balance of scientific expertise, philosophical, legal or ethical backgrounds, and lay views.
- e) ERC members, whether professional or lay members, should maintain scientific neutrality, and must not use the process of review to pursue their own agendas. All members have an equal vote in decision making.
- f) Members may include scientists, researchers, ethicists, educationist, journalists, anthropologists, lawyers, and other useful disciplines, including psychology, sociology, and statistics.
- g) Members should be able to understand the ethical principles of research and research methods, research contexts, and the practicalities of carrying out research in the social sciences, humanities, and arts.
- h) Members must be able to make their own independent judgments when considering the ethical issues involved in the research proposals placed before them.

5. MEETINGS

- 5.1 Committee meetings will be scheduled once a month, on every third Friday. As the number of applications for social sciences and humanities typically do not exceed more than 12-15 a year, the occurrence of meetings will depend on the number of applications under review. If there are no applications to be reviewed during a particular month, the meeting may be deferred.
- 5.2 The committee will concern itself with the quality and relevance of the ethical review and will follow the principles of ethics, which are provided in the policy guidelines.

6. TRAINING THE ETHICS REVIEW COMMITTEE

Training on the ethical aspects of health-related research with human participants, ethical considerations that apply to different types of research, and guidance on how ERC conducts its review of research, will be provided to ERC members when they join the committee and periodically during their committee service. Training will be provided to ERC members, either directly by the appointing entity or through cooperative arrangements with other ERCs and/or organizations that provide education on research ethics.

7. EVALUATING THE WORK OF ERC –SSHA

- 7.1 Evaluations will be conducted by knowledgeable and unbiased people at regular, pre-defined intervals, using a pre-defined format. Internal assessments will be supplemented periodically by independent, external evaluations.
- 7.2 The entity establishing the ERC should be committed to consider and, when appropriate, follow up on the findings and recommendations of internal and external evaluators.
- 7.3 The results of the evaluation should be of a type that can aid the ERC in reviewing its practices and appraising its performance (rather than apportioning blame), while also assuring the public that research is being reviewed according to established international standards.

- 7.4 Researchers, research participants, and other interested parties should have a means of lodging complaints about the ERC. Such complaints should be reviewed by an entity other than the ERC itself, such as the ERB, and appropriate follow-up actions should be taken.
- 7.5 Researchers have a means of discussing concerns with ERC members at ERC meetings, both on general matters and in response to ERC decisions on particular research studies.

8. COUNTRY REGULATIONS

- 8.1 The committee is global and cuts across different campuses of AKU, in the different countries where it operates. For the time being, the committee will review proposals from the UK, Pakistan and Kenya but is expected to eventually include faculty from Tanzania, Uganda and Afghanistan.
- 8.2 In Kenya, there will be only one ERC as per the Commission for University Education (CUE), the national accreditation body. There will be two signatories on the clearance certificate: One signatory from Kenya, according to CUE regulations, and a second signature by the Chair of this committee. Researchers will also be required to apply for a research permit from NACOSTI that accredits research institutions and approves all scientific research in Kenya.
- 8.3 Researchers in Uganda will be required to apply for a research permit from the National Council for Science and Technology (UNCST) that accredits research institutions and approves all scientific research in Uganda.
- 8.4 Researchers in Tanzania will be required to apply for a letter of approval from the Commission for Science and Technology (COSTECH) that accredits research institutions and approves all scientific research in Tanzania.
- 8.5 All Principal Investigators/ study coordinators should confirm to the committee when they have obtained their research permits/ letter for approval from the relevant National bodies (if required).
- 8.6 In Pakistan and the UK, the Chair will sign clearance letters for ERC-SSHA applications.

9. STUDENT APPLICATIONS

- 9.1 Student ethics reviews will devolve to the level of the entities in accordance with AKU policy.
- 9.2 The *ad hoc* Student Ethics Review Committee will consider the application, approve or reject it, and submit a report to ERC-SSHA.
- 9.3 Doctoral students will follow the same procedure as followed by faculty and staff and will submit their proposals to this committee.

- 9.4 To localize student applications at the Master's level and below, IED, ISMC and GSMC will establish small *ad hoc* committees, which will review applications and send reports to ERC-SSHA.
- 9.5 Students will submit their applications to the aforementioned *ad hoc* committee once their proposals have been signed off by their supervisors.
- 9.6 One of the members of ERC-SSHA will be delegated to serve on the *ad hoc* committee to ensure the quality of work.

10. ETHICAL REVIEW COMMITTEE RESOURCES:

There should be adequate resources, including staffing, facilities, and financial resources, to allow ERC-SSHA to effectively carry out its responsibilities. These include:

- 10.1 One full time staff member with adequate training to enable committee requirements and carry out technical and administrative responsibilities.
- 10.2 Adequate resources for this staff member to fulfil his/her assigned functions, including office space and equipment and supplies (e.g. computer, internet access, stationary, telephone, photocopying machines, shredding machine) to conduct administrative work.
- 10.3 Appropriate space for the committee to meet and adequate means for members to communicate as needed between meetings.
- 10.4 Financial resources to permit the committee to produce high quality work.

11. INDEPENDENCE OF ETHICS REVIEW COMMITTEES

- 11.1 ERC-SSHA must maintain independence in its operations in order to protect decision making from influence by any individual or entity that sponsors, conducts, or hosts the research it reviews.
- 11.2 ERC members (including the Chair) should remove themselves from the review process of any research in which they or close family members have a conflict of interest.
- 11.3 To ensure that the ERC cannot be influenced to approve or disapprove particular protocols, the following should be ensured:
 - a) ERC membership must include at least one person with no connection to the organization that sponsors or conducts the research under review.
 - b) Researchers, sponsors, and funders may attend an ERC meeting to answer questions about their research protocols and associated documents, but they may not be present when the ERC decides on their proposed research.
 - c) Entities that established the ERCs must ensure that members are protected from retaliation based on positions taken with respect to ERC-related matters or review of research projects.
 - d) Applications by or involving ERC members should be reviewed by at

least one reviewer who is not from the same AKU entity as the ERC member applying, and the ERC member involved with the application should not be present during ERC decisions on the application.

- e) Where the Chair is party to an application, the allocation of reviewers should be made by the Vice-Chair or by the ERC following the same protocol as (d).

12. TRANSPARENCY, ACCOUNTABILITY AND QUALITY OF THE RESEARCH ETHICS COMMITTEE

- 12.1 ERC-SSHA is accountable and answers to the Ethical Review Board (ERB). Mechanisms should exist to make ERC operations transparent, accountable, consistent, and of high quality.
- 12.2 The entity establishing the ERC should employ reliable means to evaluate whether the staff and members of the ERC routinely follow the ERC's policies, rules, and written procedures, with special attention to whether ethical considerations articulated in international guidelines and national standards are being considered and applied consistently and coherently.
- 12.3 Such evaluations are conducted by knowledgeable and unbiased people at regular, pre-defined intervals using a pre-defined format; internal assessments are supplemented periodically by independent external evaluations.
- 12.4 The entity establishing the ERC should be committed to consider and, when appropriate, follow up on the findings and ERC recommendations of the internal and external evaluators.
- 12.5 The results of the evaluation should be of a type that can aid the ERC in reviewing its practices and appraise its performance (rather than apportioning blame), while also assuring the public that research is being reviewed according to established standards.
- 12.6 Researchers, research participants, and other interested parties should have a means of lodging complaints about the ERC; such complaints should be reviewed by an entity other than the ERC itself, and appropriate follow-up actions should be taken. The ERB has that function.
- 12.7 Researchers have a means of discussing concerns with ERC members, both on general matters and in response to ERC decisions on particular research studies.

13. ETHICAL REVIEW PATHWAYS/PROCESS

- 13.1 The process for a full review comprises the following:
 - a) The ERC-SSHA Secretary will receive applications and conduct an initial review of the completeness of the application form and ancillary documents.
 - b) The Secretary will assign an application number and send an acknowledgment to the applicant.
 - c) The Secretary will forward the application with related documents to the ERC-SSHA Chair and Vice-Chair.

- d) The Chair, Vice-Chair, and Secretary will identify two reviewers who will be designated and formally assigned as reviewers by the ERC Chair and Vice Chair, on the basis of their expertise. The two reviewers must not have either a vested interest in the study (i.e. be named as an investigator or have a supervisory or advisory role) or a conflict of interest (i.e. be involved in the research or in research that competes with the research proposal or application under review or have a financial interest in the sponsor or the outcome of the research). Where possible, at least one reviewer should be from outside of the entity that is submitting the application.
- e) Applications should be made at least two weeks before the committee's monthly meeting. Applications submitted later than this will be considered at the following meeting.
- f) The reviewers will evaluate the ethical merit of the proposal and may also comment on the scientific/methodology aspects of the proposal. The ERC Secretary will collect written reports/comments from the reviewers prior to the committee meeting. (The review period is 15 days and reviewers are requested to submit their comments to the ERC Secretary within 15 days.)
- g) Comments will be shared with the ERC Chair, Vice Chair and committee members prior to the next meeting.
- h) Decision making process: Applications and revisions will be reviewed by the reviewers. If there are no concerns raised by either reviewer at the application or revisions/resubmission stage, then approval can be granted by the Chair. If there are unresolved concerns by either reviewers or the Chair, then the reviewer or Chair will share these concerns during the monthly meeting for a decision by the committee.
- i) The committee will make a decision within one of three categories: "approved"; "approved with (minor or major) revision(s)"; or "not approved".
- j) Applications with minor/major recommendations for revision must be resubmitted for formal approval to be granted.

13.2 An expedited review is defined as the accelerated review of an application by the ERC Chair/Vice-Chair or by one or more experienced reviewers designated by the Chair from among members of the ERC. In reviewing the research proposal, the reviewers may exercise all of the authority of the ERC except that the reviewers may not contest the goals of the research. A research activity may be contested only after review in a full committee sitting. The ERC may use the expedited review procedure to review the following:

- a) Certain kinds of research involving only minimal risk. Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life.
- b) Minor changes in previously approved research during the period for which approval is authorized.
- c) The decision of any expedited reviews shall be tabled for ratification at the next ERC meeting.

13.3 Applications are exempt from the full ERC review process where human subjects are not involved directly, or where there are no ambitions to publish the research. However, the committee will review any applications during which data from human subjects will be gathered or systematised. Literature reviews do not require ethical review. A letter of exemption can, if necessary for the researcher, be issued by ERC-SSHA. Applicants

must submit their application for Exemption of Studies from Ethical Review on the prescribed form, along with their detailed proposal, and other related documents. The ERC may not review studies retrospectively. If an exemption letter is required, the researcher(s) must receive an exemption letter from the ERC *before* starting the study.

14 POST-APPROVAL RESPONSIBILITIES FOR PRINCIPAL INVESTIGATORS

14.1 Follow-up procedures:

- a) Submission of progress report after six months.
- b) Submission of annual report/extension request or request for amendments
- c) Applications requesting for extensions should be submitted to the ERC Secretary who will forward the application and related documents to the Chair and the Vice-Chair to consider the following options:
 - *Option 1:* The Chair and the Vice Chair may take a decision and table it for ratification at the next ERC meeting.
 - *Option 2:* The Chair and the Vice Chair may circulate the request to ERC members and ask for an online decision.
 - *Option 3:* If the ERC is due to meet within 10 working days, the application may be decided upon at the meeting.
- d) Any amendment to the protocol should be resubmitted for renewed approval. This includes changes and/or the addition of investigators/site; in such circumstances, applications should be resubmitted for approval.
- e) Any new information related to the study should be communicated with the ERC.
- f) Any serious breach of the approved ethical protocols should be reported as soon as it occurs, and no later than within 48 hours.
- g) Premature termination of a study must be reported and explained to the ERC.
- h) The ERC may adopt any additional appropriate mechanisms for monitoring as deemed necessary.

15 RECORD KEEPING

15.1 The ERC Secretary shall prepare and maintain records of the ERC's activities, including:

- a) Agendas and minutes of all meetings of the ERC-SSHA
- b) Curriculum Vitae (CV) of all members of ERC-SSHA
- c) Updated Training Certificates
- d) A record of study protocols with enclosed documents, progress reports, and SAEs
- e) A record of all existing relevant national and international guidelines on research ethics and laws along with amendments
- f) A record of all correspondence with members, researchers and other regulatory bodies
- g) The final report of the approved projects

15.2 The ERC-SSHA secretary shall prepare and maintain a record for each application received, and any relevant correspondence, including missives between the applicant and the ERC-SSHA.

15.3 Records shall be kept securely and confidentially in accordance with acceptable data protection requirements.

15.4 Records shall be held for sufficient time to allow for future reference. The criteria for length of storage shall be guided by the AKU's quality management procedures.

15.5 The minimum period for retention shall follow institutional guidelines on records management.