THE AGA KHAN UNIVERSITY

Policy No. ORGS/001/2025 **POLICY ON CODE OF GOOD RESEARCH PRACTICE AND ACCESS TO PARTICIPANTS DATA[1]**	
Revised on	July 24, 2025
Approving Authority	University Research Council
Contact Office	Office of Research & Graduate Studies
Related Policies	*This document should be read in conjunction with the University policies on* Research Misconduct, Intellectual Property Rights, Authorship Policy and Publications Policy

The Aga Khan University in this document means its schools, colleges and hospitals operating across all campuses around the globe. This document is intended for all AKU faculty, staff, including persons with honorary positions, and students carrying out research at, or on behalf of the University.

Individuals who fail to maintain the high standards of research practice outlined in this Code of Good Research Practice may be subject to investigation and may ultimately face disciplinary.

1.0 Preamble

1.1 The purpose of this Code is to facilitate faculty, students and residents in accessing and using institutional or (outside) researcher data for their research[2] while, at the same time, ensuring that adequate safeguards are in place to protect the confidentiality and the interests of the research participants. This Code also ensures that the quality and integrity of the research are not compromised and that relevant University policies such as Intellectual Property Rights, Authorship Policy and HIPAA[3] Privacy Rule (the last for health domain studies) are followed in letter and spirit. This Policy applies to all research involving human research participants and/or their data across all research disciplines. Strict adherence to Ethics Research Committee (ERC) guidelines and conditions is required for all such research. In addition, compliance with the HIPAA Privacy Rule (for research in health domains) and/or TCPS2 (Footnote 2) is to be maintained for appropriate protection and privacy of participants' data.

1 Formerly known as Policy on Code of Good Research Practice and Access to Patient Data; Developed: April 26, 2006; Approved: June 5, 2008; Last updated: August 2, 2013.

2 Research is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation (https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter1-chapitre1.html).

3 HIPAA = The Health Insurance Portability and Accountability Act of 1996: https://www.cdc.gov/phlp/php/resources/health-insurance-portability-and-accountability-act-of-1996-hipaa.html.

When requesting access to participants' data or entering into a Data Transfer Agreement (DTA) with an external collaborator, the investigators will obtain approval from the ERC, such approval to include the determination that each institute/hospital has human ethics protections equivalent to those of the AKU and that the institute/hospital complies with the HIPAA Privacy Rule for health domain studies.

1.2 This Code is applicable to:

i. Students enrolled in programmes at AKU, including postgraduate trainees (residents, fellow), graduate (PhD, Masters, MPhil) students, fellows and postdoctoral fellows.

ii. Students engaged in research elective/exchange studies at AKU and working under supervision of AKU faculty.

iii. Faculty and staff involved in research on human subjects but who have not contributed in generating data.

2.0 Ownership and Access to Data

2.1 Any data generated or stored by AKU and all other data collected from within AKU, irrespective of the underlying reason (including research studies), whether in the form of written records or in electronic format, wherever located in different AKU campuses, are the property of the University. Appropriate data stewardship is paramount in AKU research endeavours.

2.1.1 Access to such data will require explicit approval by the competent authorities, such as the University's Ethics Review Committee (ERC) and the Medical Director (for clinic/hospital records), or the Steering Committee (or equivalent) of the research project. In all cases, the identity of the participants must at all times be kept confidential.

2.1.2 The physical form of the data, including participant medical records and biological samples, may be kept within the department(s) responsible for generating the data and for updating/maintaining it. Transfer or shipment of bodily fluids and materials require official clearance by accepted University authorities as stated in 2.1.1.

2.1.3 Researchers generating or collecting participant-related data as a part of their research project shall be responsible for its integrity, security and confidentiality. Any other person interested in using the data must seek formal consent from the Principal Investigator, the Ethics Review Committee and/or the Research Office, as appropriate.

2.1.4 The use of electronic data capture and retention requires special care, that care being guided by the items in Section 6, below.

2.2 Access to data should normally not be denied to any member of a research group which collected the data. However, the formation of writing groups should follow the publications policy specified for the project. Individuals outside the research group should be allowed access to data only after agreement of the group members, approval from the primary supervisor/principal investigator and acquisition of ERC approval.

2.3 Each undergraduate student, graduate student, postgraduate trainee and postdoctoral fellow or other investigator in a research project should come to an understanding with the primary supervisor or Principal Investigator, preferably in writing, about which parts of the project he/she might continue to explore after leaving the research project. Such an understanding should specify the extent to which a copy of the research data may be taken and should stipulate the need for ERC approval for such further data use.

2.3.1 In all cases, there must be no data security breach. Co-investigators at other institutions are entitled to access the data if they participated in its generation.

2.3.2 In all such cases, prior permission of the Section/Department Head and the Medical Director will be required for patient data in the health domain.

2.4 Where the supervisor or other collaborators and the student have jointly generated data and/or results that have been published, the student may incorporate the data in his/her dissertation or thesis, for which he/she will have the copyright, with the permission of the other data co-owners.

2.4.1 Permission to use data in the student's thesis, however, does not give the student the right to use the data for other purposes without permission from the primary supervisor. The primary supervisor will ensure that applicable rules (such as ERC approval) are followed prior to granting such permission.

2.5 All communications and publications generated out of students' work, must at all times state the student's supervisor as the corresponding author. The student will, however, remain the principal author of all such publications (see AKU Authorship Policy).

2.6 All student-related projects/assignments and/or elective studies whether a part of regular curricula or optional, which require access to clinical data or participants' interaction, must be coordinated through the primary supervisor and relevant authority (as in 2.1.3).

3.0 Procedure to Access Participant Data

3.1 All faculty, fellows, postdoctoral fellows, residents, students (undergraduate and graduate) and staff who intend to use patient medical records, other participant data or any other source of participant information, such as computer-generated data for research, must fill in the request form available from the Research Office.

3.1.1 As stated in the instructions, the form must be duly signed by the respective unit/Department Head before it is submitted to the Chief Medical Officer or his/her equivalent.

3.1.2 Except for purposes of clinical audit, system or service evaluation, all other studies requiring access to participant data will require an approval from the ERC. However, if the intention is to publish the clinical audit, system or service evaluation (Quality Assurance/Quality Improvement (QA/QI)) study as a research publication, then ERC approval is necessary prior to the commencement of the study as it is against ERC policy to review studies retrospectively.

3.1.2.1 Principal Investigators are advised to submit a request for exemption from ERC review, if the study qualifies for exemption. This endorsement can then be submitted to journal editors, if required for publishing a paper.

3.1.3 Requests for access to records from specially created databases should be submitted to the Steering/Executive Committee responsible for the database. Again, ERC review of the use of such accessed data will be required.

3.2 Students and postgraduate trainees engaged in research projects as part of their undergraduate or graduate coursework will require approval of their supervisor and the unit Head of the respective discipline as well as ERC approval. They will be required to sign an undertaking that the data generated from the project will not be presented in a conference or submitted for publication without the explicit approval of their respective primary supervisor.

3.3 Consistent with the understanding that all data belongs to the University, students are required to submit to their supervisor(s), a copy of the final report from the data generated.

4.0 Retention of Research Data and Records

4.1 The researcher should put in place a Data Management Plan[4] to describe the collection, handling, sharing, and storage of data through the lifecycle of the research project and beyond. Researchers will follow the best practices for data management and the expected standards within their discipline.

4.2 The Data Management Plan will stipulate the form in which the data will be retained (typically, the original form of the collected data will be retained up to the minimum retention time-limit – see following sections); after that, electronic copies may be acceptable for longer-term retention of the data.

4.3 The minimum time-limit for the retention of research data and records will be **seven (7) years**[5] from the end of the data collection for the research project, the last publication/report emanating from the research, or when a degree is awarded to a student for the research work (whichever is last). Research records include all forms of results captured in the course of the research (laboratory notebooks, questionnaires, interview and similar notes, etc). The primary purpose for the retention is to preserve the ability to validate the research findings and/or to permit the work to be repeated or extended into new scholarship (See Footnote 4).

4.4 Ethics Review Board (ERB) and Ethics Review Committee (ERC) records will similarly be retained for seven (7) years beyond the last year in which the research protocol was active.

4.5 Data from clinical trials must be retained for twenty-five (25) years.

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[4] A plan for research data management throughout the lifecycle of the research project (http://www.science.gc.ca/eic/site/063.nsf/eng/h_97610.html).

[5] Data retention times are set to provide an adequate period to allow any questions about the data to be addressed (e.g., accuracy, reproducibility, originality, etc.) and to meet any requirements of the sponsors or applicable laws or regulations. Research data and related financial data must both be considered. Retention times vary: some institutions rely on a statement similar to the preceding; others state 3 years (Oxford, Memorial Sloan Kettering), 5 years (University of British Columbia, Canadian Institutes of Health Research) or 7 years (AKU, University of Alberta [for financial records]).

4.6 Where the research requires only anonymized data, identifiable data should be anonymized as soon as possible after it is generated.

4.7 Where data involve participants who are children and/or adolescents, appropriate guidelines must be adopted[6] as approved by the ERC.

4.8 Where the research or data-matching studies require the data to remain identifiable, the identifier key should be kept separate from the research data and, if transmitted, sent independently. For both the data and the identifier key, encryption should be utilized as part of the Data Management Plan (see also Section 6, below).

4.9 Access to the retained research data will require approval by the Ethics Review Committee (ERC) as described in Section 3, above.

5.0 Retention of Human Biological Materials

5.1 Biobanks[7] are important research assets. In the same way that data preserved for possible future research work may support new insights, human biological materials can also support future research projects. The time of retention of such specimens should be decided, in part, by the stability of the material under the appropriate storage conditions.

5.1.1 Storage conditions for the human biological materials can be guided by the range of relevant policies of the AKU Department of Pathology and Laboratory Medicine or by the standard practices typically followed in a given field of study where the Materials are routinely used or studied.

5.2 Two main approaches to acquiring and using human biological materials in research can be considered:

5.2.1 When materials are to be collected for research purposes, ERC approval is required in advance. Related to that approval, is the use of a consent form for the research participants, agreeing to the collection of the tissue for the specified research purpose.

5.2.2 Tissues acquired for clinical and similar purposes may result in excess material (otherwise discarded) that can be saved. Subsequent proposed use of these materials for a research purpose requires ERC approval.

5.3 In the case where someone other than the person(s) who established the biobank, wishes to use the materials for research, a new ERC approval is needed.

5.4 When the two examples (immediately above) of secondary use of the biobank materials is requested, the ERC could waive the need for the consent of individual participants if specified conditions are met.

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[6] A Best Practices for Health Research Involving Children and Adolescents document developed to complement the TCPS2 provides guidance (https://cihr-irsc.gc.ca/e/41268.html).

[7] Biobank policy is to be developed for AKU.

5.5 Whether the biological materials are "identifiable" *versus* anonymous is important for the ERC review.

5.6 Sharing of human biological materials would require a Material Transfer Agreement to be signed following an ERC review as outlined in the Policy for Submitting Extramural Grant Applications.

6.0 Data Security when Electronic Devices and/or the Internet are Used in Research

6.1 Portable devices may be needed for the conduct of selected research. Such devices introduce security risk.

6.1.1 In general, research data should only be placed on portable devices when necessary for the needs of the research project.

6.1.2 The portable devices should be protected through:

i. Use of a password and,

ii. Data encryption.

6.1.3 If the use of the portable device in research includes travel, travel precautions/preparations should be taken including the following (in addition to the password and encryption precautions):

6.1.3.1 Do not transport sensitive information unnecessarily;

6.1.3.2 Safeguard the device from theft or damage;

6.1.3.3 Use the latest (patched) software;

6.1.3.4 Avoid wireless connections when accessing sensitive data;

6.1.3.5 In case of loss/theft/damage, report immediately to the Safety and Security Department at AKU.

6.2 Data stored on a computer that is connected to the internet should be encrypted as should data sent over the internet.

6.3 Research which includes a "cloud"[8] service, is subject to the same data management practices (*e.g.*, security, access, etc.) as other research activities that involve use of the internet.

6.4 Data repositories or registries to be used for the storage of sensitive data must be assessed for the adequacy of their security safeguards (*e.g.*, encryption of data, access regulated according to Section 3, above, etc).

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[8] A "cloud" is a remote, commercial computing service (server, storage, software, analytics, etc.) accessed via the internet.

6.5 Research conducted on the internet remains subject to a number of debates regarding ethical considerations. Researchers should follow the currently accepted approaches and practices in their research domain.

6.5.1 The design of internet research should consider distinguishing between public and private information (and the related need for ethics review) and, for those studies where ethics review is needed, obtaining free and informed consent, the protection of children & adolescents, pseudonyms & confidentiality, validity & reliability of data, anonymity & confidentiality, and risks of follow-up.

6.5.2 Research using questionnaires on the interned may not have shortcomings greater than those of other methods and may be able to be subjected to the same evaluation criteria.[9]

6.5.3 The security measures listed above for mobile and fixed computer devices should be applied to the extent possible for research that uses the internet.

7.0 Assets Purchased through Research Grants (Restricted Funds)

7.1 All assets purchased from (restricted) research funds are the property of the University.

7.2 Generally, the relevant policies of the Materials Management Division, Purchasing Department, and Finance Division are followed in the acquisition, purchasing, payment, capitalization, depreciation, management, disposal, and write-off of research-dedicated fixed assets.

7.3 Department Chairs are responsible for coordinating the acquisition planning, procurement, and the ongoing effective and efficient stewardship of assets, including safeguarding, utilization (possible re-assignment/relocation), maintenance and disposal.

8.0 Dispute Resolution

8.1 Any dispute related to access of data or misuse of data shall be referred to the Vice Provost, Research, who will be the final arbiter. Disputes related to authorship and intellectual property shall be resolved according to the procedures outlined in the respective policy document.

9 Panel on Research Ethics (Government of Canada): https://ethics.gc.ca/eng/about_us propos_de_nous.html