THE AGA KHAN UNIVERSITY

Policy No. ORGS/005/2023 **POLICY ON CODE OF GOOD RESEARCH PRACTICE AND ACCESS TO PATIENT DATA**	
Approved on	July 13, 2023
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 *Intellectual Property Rights* and *Authorship Policy*. Intended for AKU faculty and staff, including persons with honorary positions, and students carrying out research at/or on behalf of the Aga Khan University.

1.0 Preamble

1.1 The purpose of this *Code* is to facilitate faculty, students and residents in accessing and using institutional data for their research while at the same time ensuring that adequate safeguards are in place to protect the confidentiality and the interests of the patients. 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 Privacy Rule are followed in letter and spirit. In addition strict adherence to ERC guidelines and compliance with [1]HIPAA Privacy Rule is to be maintained for appropriate protection and privacy of patient data. When requesting access to patient data or entering into a Data Transfer Agreement (DTA) with an external collaborator, the investigators will ensure that each institute/hospital complies to the HIPAA Privacy Rule.

1.2 This *Code* is applicable to:

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

[1] *HIPAA = The Health Insurance Portability and Accountability Act of 1996: http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html.*

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. Access to such data will require explicit approval by the competent authorities, such as the University's Ethical 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 patient must at all times be kept confidential[2].

2.1.1 The physical form of the data, including patient 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.

2.1.2 Researchers generating or collecting patient related data as a part of their research project shall be responsible for its integrity, security and confidentiality. Any other person[3] interested in using the data must seek formal consent from the Principal Investigator, Medical Director and/or the Ethical Review Committee, as appropriate.

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 upon a justifiable and reasonable request, and approval from the primary supervisor/principal investigator.

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.

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.

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 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 are followed prior to granting such permission.

2.5 All communications, 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*)

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[2] Annas GJ. A national bill of patients' rights. *N Engl J Med 1998; 338: 695-699.*

[3] Other faculty members, students and/or residents.

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

3.0 Procedure to Access Patient Data

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

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 Medical Director.

3.1.2 Except for purposes of clinical audit, system or service evaluation, all other studies requiring access to patient data will require an approval from the ERC. However, if the intention is to publish the clinical audit, system or service evaluation 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 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 of records from specially created databases should be submitted to the Steering/Executive Committee responsible for the database.

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. 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) copy of the final report from the data generated.

4.0 Dispute Resolution

4.1 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.

Previous approval: July 29, 2013; September 12, 2013