AGA KHAN UNIVERSITY

Guidelines, Policies and Procedures

Policy Name	Policy on Mechanism for Change of Principal Investigator for On-Going Research Project
Policy Number	AKU-K/ORGS/002-2022
Approved by	Kenya University Council / Senate (KUC/S)
Date of Original Approval	
Date of Revisions	October 18, 2022
Contact	Office of Research & Graduate Studies, Grants Support Office

Scope: This policy applies to all Aga Khan University Kenya faculty and staff involved as Principal

Investigator (PI) on sponsored research projects.

Statement: It is the policy of the University that the PI and/or department head is responsible for initiating

notification of any change in PI status and all notifications must be routed to the Grants Support

Office (GSO) for review and action.

Purpose: To establish a policy and best practices for change of PI for an on-going internal/external

sponsored research project and to permit AKU-K to fulfill its obligations to the external sponsor

and for the responsible conduct of research.

Procedures: Research grants are awarded to the University, rather than to individuals. When a Principal

investigator (PI) leaves or plans to leave Aga Khan University Kenya (AKU-K), after review of the following options will (a) the project be terminated and assess consequence there off, e.g., returning funds, etc.; (b) the project be transferred to another university/institution to which the PI is planning to join; or (c) a PI from existing faculty of AKU-K be considered as a replacement. AKU-K's prime interest is to ensure that all research projects are completed. The following mechanism will be used for changing the PI on an internally or externally funded

research grant.

Conditions under which policy would be applicable and implemented:

- a) PI takes a leave of absence for more than 3 months or a quarter of the total grant period (e.g., sabbatical/sick/others).
- b) PI intends to leave the University.
- c) Death, serious illness, or injury renders the PI unable to continue work on the project.

Definitions

Extramural grant: Any project funded by an external funding agency.

Intramural grant: Any project funded by the Aga Khan University.

AKU-K sponsoring body: The committee/group authorized by AKU-K to award internal research grants,

e.g., the Grants Review Committee (in case of URC grants) or relevant entity

/department.

GSO: Grants Support Office (GSO) – A unit in the Office of Research & Graduate

Studies that provides primary administrative support for establishing sponsored

and intramural research and reports to the Associate Provost Research.

Principal Investigator: Faculty or research staff of the Aga Khan University who is approved to be the

Principal Investigator and is primarily responsible for the design, execution, management, and reporting of a research project (designated as the grantee and approved by the sponsor) and who will be involved in the project in a

significant manner.

Sponsor: A person or organization that pays for the cost of an activity in a research study.

Also known as the funding agency.

University: The Aga Khan University - Kenya or The Aga Khan University Hospital Kenya.

Process for change of PI

PI must provide a written letter of notification to the GSO with an endorsement from his/her department Chair/Director/Dean. The letter should explain the reason for requesting a change of PI and including a plan of how the research project will be completed. Written consent of the substitute PI to devote the required time should be attached. The GSO in consultation with AKU-K Legal and Finance (and other support departments if relevant) will review the sponsor's requirement for the specific situation and guide on negotiation on appropriate changes with the sponsor. Specific cases are discussed in the following sections.

A. Intramural Grants

- 1. A grant that has been approved from an AKU-K sponsoring body, including University Research Council (URC), irrespective of budget activation status and/or duration for which the grant has been active, will require notification for change of PI to GSO. GSO will then seek approval from department Chair/Dean/Director and AKU-K sponsoring body and determine if the **substitute PI is qualified** and has the experience, time and interest to complete the research project. The final decision will be communicated to relevant Finance Office by GSO after consulting all stakeholders.
- 2. If the PI goes on a short-term leave of absence of up to one quarter of the total grant period, but not exceeding three months then, **no replacement is required**. However, it is the PI's responsibility to obtain approval from the sponsoring body and inform the departmental Chair/Director or Dean and the GSO of his/her temporary absence.
- 3. Ideally, the project should be completed before the PI goes on long-term leave of absence exceeding three months (e.g., sabbatical/professional/personal/medical leave). Otherwise, the PI should formally write to

the GSO with an endorsement from departmental Chair/Director or Dean, informing of his/her long absence and with a nomination to **appoint an interim PI**. The proposed changes will then be communicated to the Institutional Scientific and Ethics Review Committee for their review and approval. For the appointment of interim PI, process for change of PI (mentioned above) should be followed.

4. If the PI leaves the University, department Chair/Director/Dean upon receiving the PI's resignation, should approach the relevant Finance Office and GSO to check the status of the research project(s) under the PI. If the resignation letter accompanies a formal request of transferring the PI's status to another colleague, then all requirements for change of PI and eligibility criteria for PI should be met. In case there is no substitute person available to take over as PI, the departmental Chair in consultation with Dean/Director, GSO and the relevant AKU-K sponsoring body may decide to assume the role of PI (partial/full) or under extraordinary circumstances may terminate the project.

B. Extramural Grants

- 1. For PI's leave of absence, please refer clause number 2 and 3 in Section A (above).
- 2. If the PI decides to leave the University, department Chair/Director/Dean upon receiving the PI's resignation, should approach the relevant Finance Office and GSO to check the status of the research project(s) under the PI.

If the resignation letter accompanies a formal request of transferring the PI's status to another colleague, then process for change of PI (mentioned above) should be followed. The substitute PI should meet eligibility criteria as per clause 3.0 of the "Policy for submitting extramural grant applications". In case there is no substitute person available to take over as PI, the departmental Chair/Director may decide to assume the role of PI (partial/full) in consultation with Dean/Entity Head and GSO or under extraordinary circumstances may terminate the project.

The Sponsor's guidelines specific to the transfer of a project to a new PI should always be followed. No changeover or modification in the status of PI shall be implemented without the written authorisation of the Sponsor. Once the approval from the Sponsor is received, a copy of the same must be sent to the GSO and the relevant Finance Office at AKU-K.

The new PI should notify in writing to the University's appropriate compliance committees (e.g., Ethical Review Committee) regarding the change in the PI's status with a copy to the departmental Head/Director and GSO. The relevant regulatory bodies outside AKU-K (e.g., National Commission for Science, Technology and Innovation – NACOSTI; Pharmacy & Poisons Board -PPB) must also be informed of this change (where applicable).

- 3. If the PI wants to transfer the research grant to another institution on which he/she is currently working, the request will be submitted to GSO with an endorsement from department chair/Dean/Director. GSO with guidance from AKU-K Legal, Finance and sponsor will assess each case and may:
 - Consider the PI's request, provided the Sponsor has allowed it and it does not unfavorably impact AKU-K in any way; or
 - Allow the PI to continue to work on the project on a part-time or honorary basis if relevant faculty within AKU-K is not willing to undertake the project; or
 - In consultation with the GSO, department Chair/Director and Dean may choose to terminate a project if it cannot be transferred to the institution where the PI is planning to join; if there is no suitable and willing substitute PI; or for any other reasons whatsoever.

4. In case the PI is allowed to transfer the project to his/her new institution;

He/she may be allowed to take his/her share of the data/samples. An appropriate Data/Material Transfer agreement should be signed as per AKU-K policy on "Code of Good Research Practice and Access to Participant Data" at https://www.AKU.edu/research/policies/Pages/home.aspx.

 AKU-K should get a written understanding/amendment to the contract from the sponsor(s) on the transfer of grant/data/material to another institution and that there are no outstanding financial obligations, or technical liabilities on AKU-K.

C. RESPONSIBILITY OF THE DEPARTMENT CHAIR

The role of the department Chair/Director is to ensure that the project would continue under the leadership of the new PI and the new PI would have sufficient time to carry out the assigned tasks. In case where the proposed PI is from another department, similar assurances will be required from the concerned departmental Chair/Director.

D. SUBSTITUTE PI CERTIFICATION:

The substitute PI will be required to sign the following statement

"I am not debarred, suspended, or proposed for debarment or suspension by any funding agency, and I agree to accept the role of PI and the responsibility for the scientific conduct and financial oversight of the project entitled, (insert title of project). I agree to provide all reports required by the Sponsor according to the specified timelines."

Provide signatures of original PI as well as the substitute PI, Chair of Dept and Entity head (as appropriate) at the bottom of the letter/certification.

APPENDIX

Specimen Letter for Change of Principal Investigator (amend as appropriate) (Must be printed on University letterhead)

Name of contact person SPONSOR Address line 1 Address line 2

Re: Nomination of Change of Principal Investigator for Grant #XXX12345, "Title of grant"

Dear [Name of contact person]

Due to [give reason from (a), (b) or (c), we are requesting the appointment of Dr. [New PI] as principal investigator for the continuation of the project, "Title of Grant."

Dr. [New PI] worked with Dr. [Original PI] on this project from its inception and has agreed to complete the work and submit final report. A copy of Dr. [New PI's] biosketch is enclosed for your review.

If you need additional information about Dr. [New PI] or the project, please let us know. We appreciate your consideration of this request to appoint Dr. New PI as PI and look forward to hearing from you soon.

Sincerely,

Institutional Signing Official Department Head/Director Original PI

Enclosure: Bio-sketch of [new PI]

Acceptance letter of [new PI]

cc: Grants Support Office (Research Office), Aga Khan University Kenya.