



RESEARCH OVERSIGHT DURING LEAVES AND AFTER RESIGNATION

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DOCUMENT TYPE

☒ Policy

☒ Procedures

SCOPE

University-Wide ☒ Departmental ☐ Specify Department(s):

PURPOSE

The purpose of this policy is to define the mechanism of maintaining oversight of research studies involving human subjects when principal investigators intend to resign or go on a temporary absence/leave from AUB

DEFINITIONS

Principal investigator: An individual approved to lead and conduct a research project or program. He/she shall be responsible and held accountable for the proper ethical conduct of a project or program, including the actions of all his/her research team members during any research activity involving human subjects taking place under the auspices of AUB and/or AUBMC. This means, but is not limited to, any research conducted on the grounds of AUB/AUBMC or utilizing the resources of AUB/AUBMC; or by an AUB faculty member irrespective of the site of the research work.

POLICY STATEMENT

1. The principal investigator (PI) is responsible for ensuring the continuous and uninterrupted management of his/her study and establishing mechanisms to address any urgent issues promptly.
2. In the event of resignation from the institution, the PI is responsible for designating/appointing an eligible AUB colleague who meets the criteria defined in the policy on "[PI Eligibility Requirements to Conduct Human Subject Research](#)" to serve as the new PI while ensuring seamless handover and timely transfer of research responsibilities, oversight of ongoing research, and care of research subjects as an integral element of the formal clearance procedure. If the study has been completed, the PI should ensure a closure form is sent before the clearance procedure.

In the event of temporary absence/leave(s) that fulfills any of the below criteria, the PI has to assign/designate an eligible AUB colleague who meets the criteria defined in the policy on "[PI Eligibility Requirements to Conduct Human Subject Research](#)" to serve as interim PI to oversee and attend to research activities until the leave concludes and the primary PI returns to his/her responsibilities at AUB.

- i. The PI's planned leave exceeds 4 months.
 - ii. The PI is unable to oversee or attend to research activities while on a leave of less than 4 months.
 - iii. The PI is in charge of interventional studies or clinical trials or any other research studies approved by the full board or convened IRB or determined to have significant risk otherwise.
 - iv. The PI is in charge of a study that involves clinical testing with the potential for reporting unexpected urgent laboratory or other diagnostic testing results.
3. The PI may continue to serve as PI for his/her study during a temporary absence/leave(s) from AUB lasting less than 4 months provided that none of the situations listed under point 3 apply and that he/she is able to adequately oversee or attend to research activities despite being on leave.

PROCEDURES:

- 1) PIs planning to go on temporary absence/leave(s) or intending to resign from the institution should arrange with an interim/new eligible PI to take over the research responsibilities and oversight of the ongoing research studies, before their planned leave/departure from the institution.
- 2) The interim/new PI must confirm his/her willingness, in writing to the former PI and IRB, to assume all PI responsibilities.
- 3) The PI shall communicate this request with the IRB through a formal amendment by submitting the following:
 - A "Modification Request" form detailing the terms of the handover, including data access, custody and handling.
 - All the required amended documents in tracked and clean versions.
 - Proof of CITI training for the interim/new PI.
- 4) The interim/new PI must be granted approval by the IRB before the former PI's leave or departure, except in cases of emergency. The IRB should be informed as soon as possible and above procedures followed as soon as feasible.

NON-COMPLIANCE

Violation of this policy will result in incidents of noncompliance, which will be addressed at the HRPP/IRB level.

RELATED POLICY DOCUMENTS

[IRB Manual](#)

[PI Eligibility Requirements to Conduct Human Subject Research](#)

OTHER INFORMATION

POLICY CATEGORY: Governance and Administration

POLICY CONTACT: HRPP- IRB Department, email: irb@aub.edu.lb extension: 5445

POLICY OWNER: HRPP Director

POLICY HISTORY AND REVIEW

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19/06/2027