



PRINCIPAL INVESTIGATOR ELIGIBILITY REQUIREMENTS TO CONDUCT HUMAN SUBJECT RESEARCH

Table of Contents

Document type	2
Scope	2
Purpose	2
Definitions.....	2
Policy Statement.....	2
Exceptions and Special Circumstances	3
Non-Compliance.....	3
Related Policy Documents.....	3
Other Information.....	4
Policy History and Review	4

DOCUMENT TYPE

Policy

Procedures

SCOPE

University-Wide Departmental Specify Department(s):

PURPOSE

The purpose of this policy is to define the criteria authorizing AUB faculty, staff, and students to assume the role of Principal Investigator (PI) for a research project involving human subjects conducted under the auspices and governed by the AUB Human Research Protection Program (HRPP) and Institutional Review Board (IRB).

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 conducted under the auspices of AUB. This means, but is not limited to, any research conducted on the grounds of AUB or AUBMC or utilizing the resources of AUB or AUBMC; or by an AUB faculty member, staff, or student irrespective of the site of the research work.

POLICY STATEMENT

Faculty and staff meeting all the criteria outlined below are eligible to serve as Principal Investigators (PI) on research projects involving human subjects:

- a. Full-time employment status at AUB per AUB definition.
- b. Holding a doctoral degree.
- c. Having completed the mandatory web-based research ethics course or any other training required by the Human Research Protection Program (HRPP) or AUB.
- d. Having one of the following academic appointments:
 - An academic rank of Professor, Associate Professor, Assistant Professor, Lecturer, and Instructor. This also applies to such titles preceded by "Emeritus", "Research" or "Clinical", or followed by "practice" or "clinical specialty".
 - Visiting faculty title (for a semester or longer) in one of the aforementioned ranks.
 - An adjunct faculty title in one of the aforementioned ranks. This requires having a full-time AUB faculty member as co-investigator for the project.

EXCEPTIONS AND SPECIAL CIRCUMSTANCES

Individuals who do not meet all the criteria outlined under the policy statement may be eligible for an exception, subject to the process outlined below:

- a. Clinical associates, research associates, academic associates, part-time faculty members, non-doctoral faculty members, doctoral-degree candidates, non-faculty doctoral-degree holders staff members, and other staff members, may be exceptionally granted the privilege of serving as a PI for exempt-level studies and some expedited-level studies including studies involving review of medical records at AUBMC and other AUB-owned sites. Interventional studies and full-board studies are excluded from consideration under this process.

Procedures:

Request for Principal Investigator Privileges:

- a. Individuals seeking consideration to serve as principal investigators on a research study shall complete and submit the following documents:
 - A signed "[Principal Investigator Status Request](#)"
 - CV inclusive of a list of publications.
 - Summary of prior research work and IRB submissions of projects involving human subjects.
- b. A formal review process will be conducted for each request by the HRPP/IRB office.
- c. A set of criteria will be applied to recommend a determination to the HRPP Director and will include but not limited to, the level of risk to both research subjects and AUB, appointment type, duration of affiliation with AUB, research expertise, involvement of AUB faculty member(s), students, staff, and the composition of the research team.
- d. The HRPP director will review the request and related documents to decide on granting the requested Principal Investigator privilege. Final approval will be granted by the HRPP Director, in coordination, when necessary, with the Dean of the respective faculty and/or the Provost.

NON-COMPLIANCE

The HRPP/IRB has the responsibility for the implementation and compliance with this policy.

RELATED POLICY DOCUMENTS

IRB Manual

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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