

Principal Investigator Requirements Policy

I. Purpose

This Policy describes the requirements to be listed as a Principal Investigator ("PI") on Institutional Review Board ("IRB") protocols for research conducted at Albert Einstein College of Medicine ("Einstein") and Montefiore Medical Center ("MMC").

II. Scope

This Policy applies to IRB protocols for research conducted at Einstein or MMC.

III. Definitions

None.

IV. Policy

The Principal Investigator at Einstein or MMC must be qualified by virtue of training and experience to serve in this role:

- The PI must be a faculty member with the rank of instructor or above; and
- The PI must be properly credentialed by the facility at which the research is approved to take place; and
- The PI must be employed (either full time or part time) by the institutions noted above; and
- If the research involves the administration of a drug or use of a device for research purposes, the PI must be a licensed physician.

Note: The PI may not be a resident, fellow, postdoctoral, or other trainee. Adjunct, visiting, and voluntary faculty may serve as a co-PI but not as PI.

Exceptions to this policy may be granted on a case-by-case basis by submitting the request to the Dean or his/her designee.

V. Effective Date

Effective as of: 15 January 2020

VI. Policy Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Policy. The Executive Dean is the Responsible Executive for this Policy. The OHRA Director is the Responsible Officer for the management of this Policy.

VII. Approved (or Revised)

ER of	12/17/2020	
Responsible Executive	Date	_