

Principal Investigators

Introduction

A Principal Investigator (PI) has full responsibility for the oversight of a research study, including the design, development and implementation of the study plan; as well as all administrative aspects, and financial and non-financial compliance aspects of the study. The PI is fully responsible for the academic quality of the research and for ensuring compliance with the terms, conditions, and policies of the sponsor and the university.

Four key elements are covered here

1. PI responsibilities and obligations
2. Compliance requirements
3. Types of NIH PI's
4. Helpful NIH information



Principal Investigators

1. PI responsibilities and obligations

Oversight of project finances

In collaboration with Administrative Directors and Grants Managers, PI's are expected to review accounts and projects on a monthly basis. In doing so, PI's confirm

- Research project staff and effort
- Financial transactions
- Subawardee progress and invoices
- Commitments and projections

PI's can access their accounts independently by viewing [My Grant Expenses](#)

Helpful Links

[BU Policies for Researchers](#)

[PI Status Request Form](#)



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2. Compliance requirements

BU conflicts of interest policy for research

BU has established [Investigator Financial Conflicts of Interest Policy for Research](#). The purpose of this policy is to uphold the highest ethical standards of objectivity in research by identifying and evaluating financial conflicts of interest (“FCOI”) that may affect research decisions, transactions and operations at BU and managing them so that important collaborations can be undertaken without compromising integrity. The policy is also intended to be consistent with the Boston Medical Center Significant Financial Conflicts of Interest in the Conduct of Research Policy. Additionally, this policy is intended to comply with the requirements of the federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94 for research funded through PHS.

Biosafety

It is the PI’s responsibility to see that researchers, technicians, students, or volunteers who work in your laboratory who have contact with animals, infectious agents, or bloodborne pathogens are medically evaluated prior to starting work. Also, that anyone working with bloodborne pathogens is offered the hepatitis B vaccination series administered by Research Occupational Health Program in compliance with the Bloodborne Pathogen Exposure Policy for Boston University/Boston Medical Center.



Human subjects

- Ensure that all research involving human subjects is submitted to and approved by the IRB before study initiation
- Ensure that anyone delegated to conduct study-related tasks is qualified and trained appropriately
- Ensure that there are adequate resources to conduct the research
- Ensure adequate supervision of any and all co-investigators and study staff
- Ensure that informed consent is obtained prior to initiating study activities
- Address concerns/questions raised by research subjects
- Implement research as it has been approved by the IRB
- Obtain prior IRB approval before implementing study changes
- Obtain informed consent/assent in accordance with the IRB approved application
- Document informed consent/assent as outlined in the IRB approved application
- Report progress of the approved protocol as often as required by the IRB
- Report any new information of risks, adverse events, unanticipated problems etc., as outlined in the IRB policies
- Disclose conflicts of interest
- Ensure that a final report is submitted to the IRB when the study is closed or completed



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3. Types of NIH PI's

Traditional Program Director/Principal Investigator (PD/PI)

The traditional NIH research project grant consists of a single Program Director/Principal Investigator (PD/PI) working with a small group of subordinates on an independent research project. Although this model clearly continues to work well and encourages creativity and productivity, it does not always work well for multidisciplinary efforts and collaboration.

Multi-PI Projects

In a Multi-PI Project, all PI's have equal responsibility and accountability for leading and directing the project. The structure and interaction of the PD/PI team will be left up to the PD/PIs and the applicant institution. More information can be found [here](#).

Contact PI

The Contact PI is responsible for communication between the PD/PIs and the NIH, but has no special authorities or responsibilities within the project team. In many ways, a contact PD/PI is analogous to a corresponding author on a publication. The Contact PD/PI must serve as a member of the PD/PI team and must meet all eligibility requirements for PD/PI status. In those projects where there is an identified project coordinator, the coordinator could serve as Contact PD/PI or that role could be assigned to another PD/PI. It will be possible, and may even be desirable, for the grantee institution to periodically designate a change in Contact PD/PI. For example, it may be desirable to rotate the role of Contact PD/PI among the multiple PD/PIs on an annual basis at the time of grant renewal.

New Investigator

A Program Director or Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a substantial NIH research award. An investigator will retain their New Investigator status if he/she receives any of the smaller research grants, training, infrastructure, and career awards that appear on [this list](#).

Early Stage Investigator (ESI)

A PD/PI who qualifies as a New Investigator is considered an Early Stage Investigator (ESI) if he/she is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent). A Program Director/Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award. A list of NIH grants that a PD/PI can hold and still be considered an ESI can be found [here](#).

Early-Established Investigator (EEI)

A Program Director / Principal Investigator (PD/PI) who is within 10 years of receiving their first substantial, independent competing NIH R01 equivalent. EEIs may be prioritized for funding of meritorious research applications if they are either

1. losing or are at risk for losing all NIH research support if they are not funded by competing awards this year, OR
2. supported by only one active award.



Don't lose your ESI Status!

The MPI award was developed to share credit among equals on research teams. In contrast, some applicants want to use MPI awards to accomplish unintended goals, for example, to elevate a junior scientist, to entice a luminary colleague who might not otherwise get involved, to add a new technical approach to the research, or to support a collaborator at another institution. However, there can be costs associated with such strategies:

- A young scientist PD/PI will lose her/his early stage investigator (ESI) status, which offers the advantage of having an application grouped with other ESIs at the initial review group meeting, a higher priority funding consideration, and sometimes a fifth year of an award.

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4. Helpful NIH information

NIH Salary Cap

NIH sets a limit on direct salary for individuals under NIH grant and cooperative agreement awards. Based on Executive Level II pay scale, this limit has been increased to \$189,600 effective January 7, 2018.

Reduction of Effort

PIs commit to a level of effort to perform the project they have proposed. For NIH awards, PIs and Key Personnel are listed on your NIH Notice of Award. The Sponsor must approve a reduction in project effort greater than 25%. For example, if your effort decreases from 20% to 10%, this is a 50% reduction and must be submitted to and approved by your NIH Program Manager.



Helpful Links

[NIH Salary Cap Guidance](#)

[NIH Reduction in Effort for Key Personnel](#)