

Title:	Principal Investigator Eligibility		
Department:	Research Management		
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners Corporate <input type="checkbox"/> Entity	<input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners Corporate Departmental	
Applies to:	Employees, Professional Staff, and Agents of Brigham and Women's Hospital ("BWH"), Massachusetts General Hospital ("MGH"), McLean Hospital ("McLean"), and Spaulding Rehabilitation Hospital ("Spaulding") who are involved with the performance, oversight or administration of sponsored projects.		
Approved by:	Peter K Markell, Chief Financial Officer and Treasurer, Partners Barbara E. Bierer M.D., Sr. V. P. Research, BWH F. Richard Bringhurst M.D., Sr. V. P. Research, MGH		
Approval Date:	May 25, 2011		
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Contact Person:	See Contact Page		

PURPOSE:

For each sponsored award, it is customary to designate a Principal Investigator (PI) who is directly responsible and accountable to the hospital and sponsor for the proper programmatic, scientific or technical conduct of the project, and its financial and day-to-day management. The purpose of this policy is to set forth the eligibility requirements as well as the general duties and responsibilities of the Principal Investigator named in an application for all sponsored project funding and the resulting sponsored project, grant, cooperative agreement, contract, subcontract or other award mechanism received by the BWH, MGH, McLean or Spaulding.

POLICY STATEMENT:

Eligibility to serve as a Principal Investigator (PI), Co-Principal Investigator (Co-PI), Multiple Principal Investigator (Multi-PI) or Project Director of a research award is a privilege limited to individuals:

- With a current BWH, MGH, McLean or Spaulding appointment or a BWH, MGH, McLean or Spaulding Institute appointment who are principally paid by the hospital or hospital Institute¹;
- Transferring to a Partners hospital with a written agreement from the institution or a letter signed by the Department Chief confirming their appointment, start date, and, if applicable, anticipated HMS academic rank;
- Who hold a faculty appointment- within the MGH Institute of Health Professions.

¹ Or hold a Partners hospital appointment paid by the Howard Hughes Medical Institute (HHMI)

Further, PI eligibility is limited to individuals who hold a minimum academic rank of Instructor or Lecturer at Harvard Medical School or are in the process of obtaining such an appointment at the time of the grant application. Individuals holding a clinical appointment are not automatically eligible to serve as a PI and will have to be considered on a case by case basis as delineated in Attachment A. Eligibility and continued service as PI are contingent upon compliance with all applicable Partners or hospital policies, as well as all federal, state and local government policies and regulations and the terms and conditions of the award.

The responsibilities that accompany Principal Investigator status may not be delegated explicitly or implicitly to individuals who do not qualify to serve as Principal Investigator or Project Director. Under the terms and conditions of most sponsored project awards, a change of PI is subject to the prior written approval of the awarding agency or sponsor.

PI eligibility and status may be revoked by the Department Chief or the Sr. Vice President of Research in the event of failure to:

- Comply with the provisions of this policy;
- Comply with the Partners Research Management policies and procedures;
- Comply with all applicable federal, state and local government policies and regulations;
- Comply with the terms and conditions of the award for which the individual has been named PI;
- Monitor all grant accounts regularly, demonstrating fiscal responsibility for all projects; or
- Maintain all sponsored project accounts in good financial standing. A pattern of accounts in deficit status that cannot be readily resolved through transfer of the overrun to an unrestricted account may result in withdrawal of the privilege to serve as Principal Investigator.

Exceptions:

Exceptions to this policy may be granted upon written request and approval by the Department Chair (PHS Chair or institutional official who has oversight responsibility for the proposed PI and for the appropriate/compliant stewardship of resulting award/account) and approval of the Senior Vice President of Research at the Partners hospital that will be administering the project. The application and procedure to apply for PI status under special circumstances exception is included as Attachment A of this policy.

Other professionals may serve as Principal Investigator (RNs, DVMs for example) when the sponsored project activities are within the scope of the individual's licensure, appointment and training, and the Department Chief has signified their approval by signing the Partners Proposal Cover Sheet or for electronic submissions via electronic signature and completion of the approval routing process in InfoEd Proposal Development (PD) at the application stage.

Certain funding programs (e.g., Individual National Research Service Awards and NIH Career Development Awards) are tailored to post-doctoral fellows/research associates who, by convention, would be named "Principal Investigator" upon receipt of the fellowship. It is understood that graduate students, post-doctoral research fellows, and other individuals who are approved to serve as a PI do so under the supervision of a responsible faculty member or mentor. The mentor has responsibility for the performance of the grant, supervision and fiscal accountability and award oversight. Department Chief approval is signified via signature on the Partners Proposal Cover Sheet or routing approval in InfoEd PD.

Resources/Space: Special attention should be given to the issue of resources necessary for successful execution of the project. Department Chief approval, certified on the Partners Proposal Cover Sheet, signifies an intended commitment on the part of the administering Department to

provide the laboratory and/or office space required by the project, as well as a statement of ability on the part of the administering Department or Division to dedicate the personnel named in the application/grant for the level of effort specified in the resulting award. The use of hospital space and resources is at the discretion of the hospital, Department Chief and/or Sr. VP of Research. Continued use of space and resources is dependent upon availability and the PI's ability to maintain eligibility to serve as a PI under the provisions of this policy and on the condition of continued employment.

Limitation of Authority:

Designation as PI, Co-PI, Multi-PI, or PD per se does not confer institutional signature authority. No such individual may sign for the institution or convey institutional concurrence to any:

- Proposal/application,
- Award (including but not limited to grants, contracts, subcontracts, fellowships, cooperative agreements and subcontracts),
- Material Transfer Agreements,
- Non-Disclosure Agreements,
- Restricted Access Data Use Agreements,
- Institutional Service Agreements or
- Any other agreement or contract on behalf of a Partners institution

Only institutional officials with board-designated signature authority or designated specific individuals in Research Management, Research Ventures and Licensing, and the Partners Clinical Research Office may sign for or commit the institution

This policy pertains only to eligibility to apply for sponsored project funding (for internal and external funding programs) and to be named as the Principal Investigator in any/all resulting awards. Investigators should consult the respective entity compliance officer, Partners Human Research Office (IRB), Institutional Animal Care and Use Committee (IACUC), Embryonic Stem Cell Research Office (ESCRO), Radiation Safety Office or the Institutional Biosafety Committee for eligibility criteria related to submission of a research or clinical study protocol for approval of human or animal research, stem cell research or work with recombinant DNA or select agents.

DEFINITIONS:

Principal Investigator

The Principal Investigator is an individual who is or becomes eligible under this policy to submit a proposal for intramural or extramural support for a research, clinical, training, or public service project. This individual will personally participate in the design, conduct and reporting of the project and will have primary responsibility for the scientific, technical, administrative and financial aspects of the project.

Co-Principal Investigator

The Co-Principal Investigator is an investigator who will share responsibility for the scientific, technical, administrative and financial aspects of the project with the Principal Investigator. Each individual named as a Co-Principal Investigator at a Partners HealthCare Entity must meet the same eligibility requirements as the Principal Investigator. The Principal Investigator may name more than one Co-Principal Investigator on a project. (See Reference section).

Multiple Principal Investigator

Multiple Principal Investigator is a term used when more than one Principal Investigator is named in an application or resulting award and

each is expected to equally share responsibility for leadership of multidisciplinary and other team science projects that are not best served by the single Principal Investigator model. When Multiple Principal Investigators are named they share the major authority and responsibility for leading and directing the project, intellectually and logistically. Each PI named is equally accountable for the proper conduct of the project including required tangible deliverables, fiscal oversight, sub-recipient monitoring and submission of all required reports including the Leadership Plan. All PIs named in the application will discuss and designate a primary point of contact who will serve as the liaison between the sponsor and the rest of the leadership team while still recognizing that all PI's are equally responsible for their projects. The presence of more than one identified PI on an application or award diminishes neither the responsibility nor the accountability of any individual PI. Multiple Principal Investigators must meet the same eligibility requirements as the Principal Investigator.

Project Director

Project Director is a term that may be used by sponsors of training or public service projects. For the purposes of this policy, the Project Director is defined as the Principal Investigator and shall assume the same responsibilities upon acceptance of this role.

PI RESPONSIBILITIES / PROCESS:

The process described below is applicable to the BWH and the MGH whose sponsored research activities are supported by Partners Research Management. McLean and Spaulding shall develop a process that mirrors this process substituting their local research administration office for Partners Research Management.

At the application stage:

Review the application guidelines, contract solicitation or program announcement to ensure applicant eligibility criteria are met for the institution and the Principal Investigator, Co-Principal Investigator, Multiple Principal Investigator or Program Director, as applicable.

Once sponsor eligibility has been determined:

- Notify pre award grants administrator (in the department and in Research Management) of intent to apply and provide a link to or copy of the submission guidelines;
- Determine if subcontractors will be needed and if so, work with RM pre-award staff to evaluate risk of engaging subcontractors being considered. Collect required proposal documents from subcontractors, ensuring that the Statement of Intent is signed by an Authorized Institutional Official at the subcontract entity;
- For paper submissions or other applications not being submitted via InfoEd PD: Complete a Partners Proposal Cover Sheet (paying attention to the assurance language that is stated just above the PI signature section as this is a compliance document)
https://resadmin.partners.org/RM_Home/Documents/forms/PartnersResearchProposalCoversheet.pdf for routing and approval to the Department Chief or designee;
- Complete the application in accordance with the sponsor's guideline and all internal grant submission policies and procedures; the latter may require the completion of internal documents that are not required by the sponsor at the proposal stage;

- Complete a Partners RM Conflict of Interest Reporting Form https://resadmin.partners.org/RM_Home/Documents/forms/COIform.pdf identifying all individuals that will be involved in the proposed project who may need to disclose a financial conflict of interest;
- Route the completed application package to your assigned pre award grants administrator in Research Management in accordance with the internal grant submission deadline policy.
- For proposals submitted via InfoEd PD; Complete the PD record (in collaboration with department administrators) and submit to the Draft Route. Log in to InfoEd using Partners NT logon, indicate acceptance of proposal and acceptance of assurance language.

At the “Just-In-Time” stage, if applicable:

- Comply with the request sent by the sponsor and compile the information requested;
- Ensure that all staff who will be working with human subjects during the course of the project have completed the required education program in the protection of human subjects;
- Ensure that all staff who will be working with animals during the course of the project have completed the required education program in animal care and use;
- Ensure that all staff who will be working with radiation during the course of the project have completed the required education program in the radiation use;
- Ensure that all staff who will be working with hazardous materials during the course of the project have completed the required bio-safety training program;
- Ensure that any/all compliance committee protocols have been written, submitted to the respective committee and the approval secured and documented;
- Notify all proposed subcontractors that a request for Just-In-Time information has been made and reconfirm their intent, willingness and ability to be engaged in the project;
- If a revised, reduced budget and justification is requested, review ability to complete original scope of work at the lower level of funding and if unable to do so, advise pre-award GA;
- Work with RM pre-award staff to finalize all information requested so it can be submitted to the sponsor.

At the award stage:

- Notify Department Chief or designee that an award has been made and confirm that the space, equipment, specialized facilities and staff/support time needed to undertake the project will be available;
- Reconfirm with all staff who will be paid by the new award that the level of effort stated in the award is available for the time period of the award and that their financial interests have not changed since the application was submitted and if there has been a change, submit a revised Partners RM Conflict of Interest Reporting Form;
- Notify all subcontractors that an award has been made and reconfirm their intent, willingness and ability to be engaged in the project;
- When the award has been activated and the PeopleSoft number received, review the award budget and work with Department Administrator to have employee data changes submitted adding staff to the new account and order start up supplies as needed and approved in the award budget.

Through the life of the award or project period, maintain all sponsored project accounts in good financial standing. A pattern of accounts in deficit status may result in withdrawal of the privilege to serve as a PI:

- Using the InSight Fund Statement, monitor the expenses posted to each award on a monthly basis to ensure that each cost is allowable (per the hospital cost principles, Partners RM Cost Charging Policy and the terms and conditions of award), allocable and reasonable;

- Work with department grants administrator to initiate cost transfers in accordance with the Partners Cost Transfer policy when costs are identified to have posted to an account in error and use the InSight Fund Statement to confirm transfers were done correctly the following month as well as to monitor the new expenses that have been incurred and posted;
- Monitor the activities at each subcontractor site to ensure that the work is being done on time and in accordance with the agreed upon scope of work;
- Monitor the expenses incurred at each subcontract site to ensure that they are within budget, allowable, reasonable and representative of timely progress on the project;
- Ensure that all deliverables both reporting and tangible (i.e.; model organisms, cell lines, restricted access data sets) are submitted to the sponsor in accordance with the terms and conditions of award;
- Ensure that any/all compliance committee approvals are maintained throughout the life of the award;
- Ensure that any changes made during the active project period that require the prior written approval of the sponsor follow the applicable approval process (such as reducing level of effort of key personnel by 25% or more);
- Ensure that data changes are done in accordance with the approved award budget and in a timely manner to remove or add staff to the project as needed;
- Ensure that eBuy requisitions are submitted in the PeopleSoft system in a timely manner and with sufficient justification to gain approval and avoid interruptions in the flow of the scope of work;
- Ensure that any changes in the financial interests of staff being paid from a sponsored project account are reported (by completing a Partners COI form and routing to Research Management) and evaluated at the progress report stage and as needed throughout the entire project period;
- Ensure that the project does not go into overdraft as this will result in a deficit that will require resolution from the PI's unrestricted account. Overdraft spending is prohibited and patterns of accelerated spending identified through monthly account monitoring activities must be addressed and rectified expeditiously. Failure to monitor and maintain each account in good standing can result in the rescinding of PI eligibility.
- In the event of a change of PI, please consult your post award grant administrator in Research Management for guidance as to how to proceed with making a request for a change of PI.
- Any time there is an exception being made to this policy, a copy of the request for exception and corresponding approval from the department chair and entity Sr. VP of Research must be uploaded in the official project record maintained in InfoEd.

In the event of Multiple PI applications/awards, the PI designated as the liaison with the sponsoring agency, sometimes referred to as the “managing” PI, and is responsible for:

- Receiving and relaying all communications between the investigators and the sponsor;
- Work with other named PI's to identify those individuals involved in the project who should disclose financial interests;
- Receiving and coordinating all communications pertaining to the award within the Partners network and the hospital;
- Work with other named PI's to ensure that all internal protocols are submitted to the applicable compliance committee(s) and that the approval is obtained and maintained;
- Work with the other named PI's to ensure that all required documentation is prepared and forwarded to the RM post award grants administrator for any actions requiring prior approval;
- Initiate and sign any correspondence going to the sponsor and route to Research Management post-award GA for institutional review, signature and submission to sponsor;

- Work with the entire project team to ensure that all deliverables are prepared and submitted to the sponsor in a timely manner.

When named PI on a training award, there is the additional responsibility of ensuring that the Responsible Conduct in Research (RCR) educational requirements are met. PIs must make certain that all trainees, fellows, participants, and scholars receiving support through any NIH Institutional Research Training Grants, Individual Fellowship Awards, Career Development Awards (Institutional and Individual), Research Education Grants, Dissertation Research Grants, or other grant programs with a training component that requires instruction in responsible conduct of research (as noted in the Funding Opportunity Announcement, including funding programs from the NSF), complete the requirements for the RCR educational program.

http://resadmin.partners.org/RM_Home/Research_Support_Depts/Research_Oversight/Partners_Research_Compliance/RCR/RCR.aspx

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

The Principal Investigator has specific responsibilities outlined in each of the Partners Research Management Policies and Procedures. Please see

http://resadmin.partners.org/RM_Home/Policies_SOPs/RM_Policies/Alphabetical/PolicySOP-RMPolicy-Alpha.aspx

REFERENCE:

The NIH Grants Policy Statement, Part I: NIH Grants—General Information;

Principal Investigator. The PI (who also may be known as the PD) is the individual, designated by the grantee, responsible for the scientific or technical aspects of the grant and for day-to-day management of the project or program. The PI is not required to be an employee of the grantee. However, because the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

The PI is a member of the grantee team responsible for ensuring compliance with the financial and administrative aspects of the award. This individual works closely with designated officials within the grantee organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support of research findings in publications, announcements, news programs, and other media; and ensures compliance with other Federal and organizational requirements. NIH encourages the PI to maintain contact with the NIH PO with respect to the scientific aspects of the project and the GMO concerning the business and administrative aspects of the award.

Co-Investigator. An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered “key personnel.” The designation of a co-investigator, if applicable, does not affect the PI’s roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS).

ATTACHMENT:

[Application to Serve as Principal Investigator under Special Circumstances](#)

DEVELOPMENT AND CONSULTATION

Reviewed by:	Original Review Date	Revision Approval Dates & Changes:
Peter K. Markell, V.P for Finance and Research Management, Partners Barbara E. Bierer, M.D., Sr. V.P., Research, BWH F. Richard Bringhurst, M.D., Sr. V.P., Research, MGH Mary H. Mitchell, Director, Research Compliance Andrew Chase, Corporate Director, Research Management & Research Finance Robin Cyr, Director, Training & Policy, Research Management	5-25-11	8/11/11 - policy applicable only to BWH, MGH, McLean & Spaulding