



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Principal Investigator Eligibility for Sponsored Research and Training Awards
Department:	Research Management
Policy Type (please check the appropriate box)	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners Corporate <input type="checkbox"/> Partners Corporate Departmental <input type="checkbox"/> Entity
Applies to:	Employees, Professional Staff and Agents of Partners HealthCare (PHS), Brigham and Women's Hospital ("BWH"), Massachusetts General Hospital ("MGH"), Massachusetts Institute of Health Professions ("IHP"), 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, Executive Vice President for Finance & Administration, Chief Financial Officer and Treasurer, PHS Anne Klibanski, MD, Chief Academic Officer, PHS Paul J. Anderson, MD, PhD, Chief Academic Officer, BWH Harry Orf, PhD., Sr. VP Research, MGH
Original Approval Date:	May 25, 2011;
Original Effective Date:	June 1, 2011
Revision Approval Date(s):	September 1, 2011; April 15, 2015
Current Revision Effective Date:	April 15, 2015
Next Review Date:	April 2018
Contact Person:	See Contact Page

KEYWORDS:

(Optional) Keywords for search function. Words or phrases not included in the policy, but potentially helpful locators for online database users.

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, in addition to the general duties and responsibilities of the PI named in an application for sponsored project funding and the

resulting sponsored project, grant, cooperative agreement, contract, subcontract or other award mechanism received by PHS, BWH, MGH, IHP, McLean or Spaulding.

DEFINITIONS:

Principal Investigator: The Principal Investigator is the individual designated by the Partners hospital or institute with the appropriate level of authority and responsibility to direct a research or training award or program supported by an external sponsor. This individual leads the design, conduct and reporting of the project and has primary responsibility for compliance with scientific, technical, administrative and financial requirements

Co-Principal Investigator or Multiple-Principal Investigator: These terms are used interchangeably when more than one PI is named in an application or resulting award and each is expected equally to share responsibility for leadership of the project. Each named-PI is equally accountable for the proper conduct of the project and compliance with all requirements.

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

Non Employee or Person-of-Interest: These terms are used interchangeably for individuals not on a Partners hospital or institute payroll who act in a research, service, education or professional development role within the organization.

POLICY STATEMENT:

Eligibility to serve as Principal Investigator, Co-Principal Investigator, Multiple Principal Investigator, or Project Director (all herein referred to as "PI") of a sponsored research or training award is a privilege limited to individuals

- With a current PHS, BWH, MGH, IHP, McLean or Spaulding appointment who are principally paid (no less than 50%) from hospital/institute funds, Harvard Medical School (HMS) endowment funds, Harvard University (Harvard) endowment or other funds, PHS funds, and/or sponsored research funds or hold a PHS hospital appointment paid by the Howard Hughes Medical Institute (HHMI);
- Who hold the rank of Lecturer, Instructor, Assistant Professor, Associate Professor, Professor or Professor in Residence at Harvard, HMS or a MGH Institute of Health Professions faculty appointment; or who are transferring to a PHS hospital or institute with a written agreement from the hospital/institute or a letter signed by the Chief or Division Chair confirming their appointment, start date, and anticipated Harvard, HMS or IHP academic rank;
- Who have the requisite training, skills, commitment and expertise to determine the intellectual direction of the research or training project as determined by the Chief or Department or Division Chair; and
- Who are able to provide appropriate oversight of the research or training project (e.g., supervise staff, monitor expenditures) to ensure all sponsor, regulatory, and institutional obligations are met.

The electronic signature of the Chief or Department or Division Chair as part of the InfoEd Proposal Development of an electronic application or signature on the Partners Proposal Cover Sheet for a paper submission certifies that the individual so-named as PI meets the eligibility criteria set forth in this policy and has the approval of the Chief or Department or Division Chair to serve in this capacity.

Individuals categorized as a “non-employee” or “person of interest” are not eligible to serve as a Principal Investigator.

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

LIMITATION OF AUTHORITY:

Designation as PI under this policy does not confer institutional signature authority to the individual so-named. A PI may not sign for the institution or convey institutional concurrence in any of the following situations or documents:

- Proposal or application;
- Award, including but not limited to grants, contracts, subcontracts fellowships, cooperative agreements or sub awards;
- 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 individuals in Partners Research Management, Innovation, and the Partners Clinical Research Office may sign for or commit the institution.

CONTINUED PI ELIGIBILITY:

Continuation of PI eligibility with no change in hospital appointment status is contingent upon compliance with all applicable Partners or hospital policies, as well as all federal, state and local government policies and regulations and individual award terms and conditions.

PI status may be revoked by the Chief or Division Chair or the Sr. Vice President of Research/equivalent position in the event of a PI’s failure to comply with

- Provisions of this policy;
- Partners Research Management policies and procedures;
- All applicable sponsor, federal, state and local government policies and regulations;
- Terms and conditions of the award for which the individual has been named PI; and
- Failure to monitor all grant accounts routinely, demonstrating fiscal responsibility for all projects.

A pattern of accounts in deficit status that cannot be resolved through transfer of the overrun to an unrestricted account may result in withdrawal of the privilege to serve as PI.

EXCEPTIONS:

Under special circumstances, exceptions may be granted extending PI privileges to individuals not otherwise eligible to serve as PI.

Approval to serve as a PI for a specific project under an exception is limited to the duration of the project period and granted upon submission of a written request on [Attachment A](#) and approval of the Chief or Department or Division Chair and the hospital or institute Senior Vice President for Research/equivalent position.

[Attachment A](#) must be submitted to the Sr. Vice President for Research/equivalent position no later than 10 working days prior to submitting the application to Partners Research Management for BWH and MGH Investigators or hospital Research Administration for McLean and Spaulding Investigators..

Nurses and Other Hospital Professionals: Other professionals, e.g., nurses, veterinarians, may serve as PI when the proposed sponsored project is within the scope of the individual's licensure, appointment and training, and the Chief or Department or Division Chair has signified his/her approval via electronic signature and completion of the approval routing process in InfoEd Proposal Development (PD) at the application stage or, for paper submissions, by signing the Partners Proposal Cover Sheet. [Attachment A](#) is not required in these situations.

Postdoctoral Fellows and Graduate Students: 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. Graduate students and postdoctoral fellows or research associates who are approved to serve as a PI by the Chief or Department or Division Chair may do so only under the supervision of a responsible faculty member or mentor who has met the PI eligibility requirements. In agreeing to serve as mentor, this individual is responsible for the performance of the grant, supervision and fiscal accountability, and award oversight. [Attachment A](#) is not required in these situations.

PI ON AWARDS TO PARTNERS HEALTHCARE (PHS):

While the majority of research is conducted primarily at the hospitals, on occasion an investigator may intend to submit a grant proposal for research that will be carried out on a system-wide basis within PHS rather than a Partners hospital. These applications/proposals must be approved by the PHS Chief Academic Officer (CAO) and hospital Sr. Vice Presidents for Research/equivalent position no less than 10 working days prior to submission to PHS Research Management and the funding agency. The individual named as PI of the PHS project must meet the PI eligibility requirements set forth in this policy. Other professionals may serve as PI of a PHS project when the proposed sponsored project is within the scope of the individual's licensure, appointment and/or training, and the PHS Department Head has signified his/her approval via electronic signature and completion of the approval routing process in InfoEd Proposal Development (PD) at the application stage or, for paper submissions, by signing the Partners Proposal Cover Sheet. [Attachment A](#) is not required in these situations.

CHANGE IN EMPLOYMENT/CONTINUATION OF PI ELIGIBILITY:

Investigators leaving a Partners institution (i.e., no longer employed by the Partners institution) are expected to transfer their awards to their new institution or name a qualified Partners investigator to assume PI responsibilities of the Partners grant or contract and work with Partners Research Management to secure sponsor approval. The departing investigator may remain affiliated with the study in a different capacity.

Under rare circumstances, a departing PI may be granted an exception to continue as PI of a Partners grant or contract. Such requests must be submitted on [Attachment A](#) and include, in accordance with the PI responsibilities identified in [Attachment B](#), a detailed, written justification that addresses how appropriate involvement and oversight will be assured after the PI has moved to a new institution. The investigator must also provide documentation of his/her new institution's approval of the proposed plan that includes the signature of an institutional official. The exception request must be reviewed and approved by the Chief or Department or Division Chair and the Sr. Vice President for Research/equivalent position prior to the individual's departure.

If the exception is approved, the PI is responsible for obtaining all necessary regulatory approvals at his/her new institution for any involvement in research continuing at a Partners institution and for working with the appropriate hospital and Partners offices to execute appropriate agreements with the new institution to address the transfer of data and/or specimens between the institutions, intellectual property rights, and publication rights related to the ongoing research at the Partners institution. The PI is also responsible for working with Partners Research Management to obtain sponsor approval of the arrangement.

REDUCTION IN PARTNERS HOSPITAL EMPLOYMENT/APPOINTMENT STATUS/CONTINUATION OF PI ELIGIBILITY:

Continuation of PI status for individuals who are employed at a Partners hospital or institute but whose appointment is reduced to less than 50% must be reviewed and approved by the Chief or Department or Division Chair and Sr. Vice President/equivalent position prior to the individual's change in appointment.

At least 30 days prior to change in status, the PI in question must submit a continuation request on [Attachment A](#) and include a detailed, written justification for continuation of PI status that addresses if/how the investigator's effort will be adjusted to accommodate the change in appointment while ensuring appropriate involvement with and oversight of the research project. If the PI is reducing his/her appointment because s/he is changing his/her primary employment to another institution, the PI must explain how responsibilities will be split between the two institutions. If the exception is approved, the PI is responsible for obtaining all necessary regulatory approvals at his/her new institution for any involvement in research continuing at a Partners institution. In addition, the PI must work with the appropriate hospital or institute and Partners offices to execute appropriate agreements with the new institution to address the transfer of data and/or specimens between the institutions, intellectual property rights, and publication rights related to the ongoing research at Partners institution. The PI is also responsible for working with Partners Research Management to obtain sponsor approval of the arrangement.

RESOURCES/SPACE COMMITMENTS:

Special attention should be given to consideration of resources and space necessary for successful execution of a sponsored research or training project.

Department or Division Chief approval, certified on the Partners Proposal Cover Sheet or InfoEd proposal routing workflow, 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/equivalent position. 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 condition of continued employment.

POLICY APPLICABILITY TO PROJECTS SUBJECT TO REVIEW AND APPROVAL OF THE INSTITUTIONAL REVIEW BOARD (IRB), INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC), EMBRYONIC STEM CELL RESEARCH OFFICE (ESCRO), RADIATION SAFETY OFFICE, AND INSTITUTIONAL BIOSAFETY COMMITTEE (IBC):

This policy pertains only to eligibility to apply for sponsored project funding (for internal and external funding programs) and to be named as the PI in any/all resulting awards. Investigators should consult their hospital/institute Human Research Office (IRB), Institutional Animal Care and Use Committee (IACUC), Embryonic Stem Cell Research Office (ESCRO), Radiation Safety Office or the Partners Institutional Biosafety Committee (PIBC) 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.

PI RESPONSIBILITIES:

See [Attachment B](#) for general PI responsibilities applicable to all sponsored research and training awards.

NIH Institutional Training Awards (e.g., T32, K12): In addition to the responsibilities outlined in [Attachment B](#), a NIH institutional training grant PI is also responsible for ensuring that all trainees fulfill the [Partners Responsible Conduct of Research \(RCR\) educational requirements](#).

Contacts

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DEVELOPMENT AND CONSULTATION

Reviewed by:	Original Review Date	Revision Approval Dates & Changes:
Peter K. Markell, V.P for Finance and Research Management, PHS Barbara E. Bierer, M.D., Sr. V.P., Research, BWH F. Richard Bringham, 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
PI Eligibility Work Group/Research Compliance Officers Forum Andrew Chase, VP/Research Management, PHS Mary H. Mitchell, Corporate Director, Research Compliance, PHS Anne Klibanski, MD, Chief Academic Officer, PHS Christopher Clark, Office of General Counsel, PHS Peter K. Markell, Exec VP/CFO/Treasurer, PHS Paul Anderson, MD, PhD, Chief Academic Officer, BWH Shelly Greenfield, MD, Chief Academic Officer, McLean Harry Orf, PhD., Sr VP/Research, MGH Scott Rauch, President, McLean Ross Zafonte, DO, VP Medical/Research Affairs, SRN Alex Johnson, PhD, Provost/Academic VP, IHP		7/8/14, 10/17/14 10/30/14 10/30/14 11/14/14 12/3/14 12/18/14 3/4/15 1/3/15 3/4/15 2/11/15 1/21/15

