

Eligibility to Serve as a Principal Investigator for Research Involving Human Subjects

VPR POLICY I.1.1

Volume I, Research Administration
Chapter 1, Human Subjects Research
Issuing Office: Office of Vice Provost for Research
Responsible Officer: Human Protection Administrator
Responsible Office: Office of Research Administration
Originally Issued: April 2000
Most Recently Revised: March 24, 2004

Statement of Policy

Tenured or tenure track Purdue faculty, including emeriti, who are certified by Purdue University as having received training in the conduct of research using human subjects are eligible to serve as principal investigators (PI) for Purdue projects involving human research subjects. Other faculty and staff members who fall into one of the following categories *may* be eligible to serve as PI with approval from the Vice Provost for Research (Institutional Official):

1. Non-tenure track faculty, and other senior academic staff whose appointments include responsibility for the direct, independent design and direction of research;
2. Clinical faculty;
3. Senior administrative staff with appointments as Director (or equivalent) and responsibility for the direct, independent design and management of projects; and,
4. Visiting faculty.

PI status may be limited to a specific research protocol (project) or activities associated with a specific grant, or have other conditions or limitations associated with approval.

Graduate and undergraduate students shall not be permitted to serve as a PI for research protocols involving human research subjects. Purdue employees, who may otherwise be eligible under the above categories to be considered for PI status, cannot serve as a PI for a research protocol involving human subjects when they are conducting the research project as partial fulfillment of their graduate student obligations or training. When Purdue employees wish to conduct research involving human subjects as part of their graduate or undergraduate program, their faculty advisor must serve as the PI of record for the research protocol and application.

Being granted status as principal investigator for research projects involving human subjects does not imply that an individual may also serve as sole principal investigator for submission of proposals to external sponsors through Sponsored Program Services.

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The Department Head or other appropriate supervising administrator has the responsibility to ensure compliance by Purdue principal investigators and is required to maintain all documents as referenced by Purdue policies upon departure of the principal investigator, if departure is less than three years since the completion of the research project for which PI status was granted. If the research project involved the use of Private Health Information (PHI), then the records must be kept for six years after the termination of the project.

Reason for Policy

Purdue University is committed to safeguarding the rights and welfare of all individuals who serve as subjects in research conducted by agents of the University. To accomplish this goal, the University reserves the right to review and approve the training and experience of individuals who wish to assume leadership responsibilities for research with human subjects before granting status as principal investigator.

Procedures

Prior to July 1, 2004

Investigators who wish to serve as principal investigators for research involving human subjects initiated prior to July 1, 2004 are referred to the Policy on PI Eligibility dated April 2000 for information on who can serve as a principal investigator and the process by which faculty and staff other than tenured or tenure track faculty can apply for human subject research principal investigator status.

All Purdue tenured or tenure track faculty, including emeriti, who are listed as the PI of record on one or more active Purdue IRB-approved human subjects research protocols on June 30, 2004, will retain their eligibility to serve as PIs, and will be certified to conduct human subjects research at Purdue.

Purdue staff and non-tenure track faculty who have been approved as principal investigators by the Vice Provost for Research and who are listed as the PI of record on one or more active Purdue IRB-approved human subjects research protocols on June 30, 2004, will retain their eligibility to serve as PIs under the same conditions as they were approved and will be certified to conduct human subjects research at Purdue.

Cooperative Extension Service Field Extension Educators who are designated as an Extension Educator Investigator for a human subject research protocol reviewed and determined exempt by the Extension Human Subjects Advisory Committee (EHSAC) on June 30, 2004 will retain their eligibility status as investigators for human subjects research and will be certified to conduct exempt level human subjects research at Purdue.

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On or after July 1, 2004

Beginning on July 1, 2004 tenured or tenure track Purdue faculty, including emeriti, who wish to serve as PI for a new research protocol involving human subjects and have not been previously certified must become certified as trained in the conduct of human subjects research in order to serve as PI. Tenured or tenure track faculty, including emeritus faculty, must complete specific on-line education *and* workshop training activities in order to be eligible to serve as PI for a human subjects research application and protocol submitted to a Purdue IRB. Information on the specific education and training required for principal investigators and key personnel is available in the Education Policy for Investigators Conducting Human Subjects Research (VPR Policy I.1.2) or from the Purdue Human Research Participants Protection Program, Office of Research Administration or the IRB Administrator.

Beginning on July 1, 2004, non-tenure track faculty and other senior academic staff whose appointments include responsibility for the direct, independent design and direction of research; clinical faculty; senior administrative staff with appointments as Director (or equivalent) and responsibility for the direct, independent design and management of projects; and visiting professors, who wish to serve as principal investigator for research involving human subjects should follow the application procedure described below.

In addition to completing the same education and training as required for tenure track, tenured, and emeritus faculty as described in the Education Policy for Investigators Conducting Human Subjects Research (VPR Policy I.1.2), individuals holding the above listed appointments, who wish to serve as PI for research involving human subjects, must submit the documents as listed below to the Human Protection Administrator, Office of Research Administration for review.

1. Letter of support and recommendation for PI status from the appropriate authority (supervisor):
 - a. Non-tenure track faculty, clinical faculty, and senior academic staff, letter must come from the Department Head or other supervising administrator of the unit in which the individual is employed;
 - b. Senior administrative staff with appointments as Director, letter must come from the Dean or Vice President or Vice Provost administratively responsible for the unit in which the individual is employed;
 - c. Visiting professors, the letter must come from the Department Head of the unit in which the individual is appointed.

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2. Current curriculum vitae and description of experience in the conduct of research involving human subjects (if applicable).
 3. Documentation of training in the conduct of human subjects research for institutional certification.
 4. Endorsement of the recommendation by the Principal Investigator, if the proposed research is a component of a funded sponsored project for which the applicant is not the PI.

The Human Protection Administrator, Office of Research Administration will review submitted credentials for completeness and makes a recommendation for action to the Vice Provost for Research (Institutional Official).

The Vice Provost for Research (Institutional Official) will approve, approve with conditions, or deny the application, and will inform the Human Protection Administrator, Office of Research Administration, who will in turn notify the appropriate parties of the decision.

Beginning on July 1, 2004, Cooperative Extension Service Field Extension Educators not previously designated as Extension Educator Investigators may be so designated following completion of education and training as described in the Education Policy for Investigators Conducting Human Subjects Research.

Exceptions

No exceptions.

Who Should Know This Policy

Provost
Chancellors
Vice Presidents/Vice Provosts
Deans
Associate Deans, Assistant Deans
Directors
Department Heads
Faculty
Administrative and Professional Staff
Graduate and Undergraduate Students

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Contacts

Subject	Contact	Telephone
All questions	Human Protections Administrator, Office of Research Administration	(765) 494-9322