

Education Policy
for
Conducting Human Subjects
Research

VPR POLICY I.1.2

Volume I, Research Administration
Chapter 1, Human Subjects Research
Issuing Office: Office of Vice President for Research
Responsible Officer: Human Protection Administrator
Responsible Office: Office of Research Administration
Originally Issued: May 21, 2004
Most Recently Revised: July 11, 2008

Statement of Policy

To ensure the safe and ethical conduct of research involving human subjects at Purdue University, all Purdue faculty, staff, and students who conduct research involving human subjects must be familiar with and understand the underlying ethical principles, federal and state laws and regulations, and policies and procedures that compose Purdue University's Human Research Protection Program (HRPP). To document the necessary familiarity and understanding, all Purdue faculty, staff, and students who wish to conduct research involving human subjects must be certified as having completed appropriate formal training and education before an application and protocol in which they are named will be approved or determined exempt by one of Purdue University's Institutional Review Boards, or their designees. The process by which an investigator becomes certified is described under the Procedures section.

This education policy applies to all research team members (including those unaffiliated with the University) who meet the definitions of principal investigator, key personnel, non-key personnel or personnel working with identifiable, private information involved in research activities conducted under the auspices of Purdue University regardless of the location where the research is to be conducted and regardless of the source of funds supporting the research.

Reason for Policy

Purdue University is committed to ensuring the safe and ethical conduct of research involving human subjects and to complying with all applicable federal regulations and state statutes concerning research with human subjects. Critical to ensuring safe and ethical conduct and compliance with regulations and statutes is a solid foundation of knowledge and understanding of the historical context, as well as the ethical and regulatory requirements for research involving human subjects, and specific Purdue procedures for application, review, and oversight of this research.

Since October 1, 2000, all investigators who receive Department of Health and Human Services (DHHS) sponsorship for research involving human subjects have been required to be certified by the Institution as having received training in the protection of human research participants. Purdue University supports this requirement for certification and

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believes that it should be extended to include all research involving human subjects conducted by Purdue faculty, staff, and students. In addition, this policy also applies to principal investigators who are Indiana University employees that are employed at the Indiana University-Purdue University Fort Wayne (IPFW) campus and submit their human subject research protocols to Purdue University for review. This education policy has been established to accomplish this goal of assuring and certifying training in human subject's research.

Exceptions

Under the Purdue University – Indiana University-Purdue University at Indianapolis (IUPUI) *Human Subjects in Research Cooperative Agreement* for the cooperative review of human subject's research, Purdue investigators in the Department of Pharmacy Practice, based at IUPUI must submit their human subject's research protocols for review to one of IUPUI's IRBs. In doing so, the Purdue investigator must follow all requirements and procedures of IUPUI. Therefore, for purposes of certifying education or training of Purdue Pharmacy Practice investigators in human subject's research, with appropriate documentation from the investigator, Purdue University will accept whatever training program IUPUI requires of its investigators submitting protocols for review by its IRBs.

Purdue University Cooperative Extension Service Extension Educators who wish to serve as Extension Educator Investigators must complete specific human subjects research education and training requirements as described under current procedures for certification.

Purdue University principal investigators and key personnel who can provide documentation of their successful completion of a formal educational program in the history, ethics, and regulation of human subjects research which is comparable in scope to the history, ethical, and regulatory training described under Specific Procedures, may petition the Human Protections Administrator (HPA) to accept this documentation of training in lieu of the current requirements for certification as described under current procedures.

Non-Purdue University research personnel who have been certified through their own institutional certification process and can provide documentation demonstrating that certification, will be considered certified.

Consultants on human subjects research projects who do not interact with subjects or access identifiable, private information are not required to be certified.

There are no other exceptions.

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Who Should Know This Policy

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

Specific Procedures

Current Investigators and Key Project Personnel on June 30, 2004

All Purdue University faculty and staff, and Indiana University faculty based at IPFW who are designated as a principal investigator (PI) on one or more current and active human subject research protocols approved or determined exempt by a Purdue University Institutional Review Board or another institution's IRB under an inter-institutional agreement will be considered to be *provisionally* certified and retain their eligibility status as PIs for human subjects research.

In addition, Cooperative Extension Service Extension Educators, who are designated as Extension Educator Investigators for one or more active human subject research protocols reviewed and determined exempt by the Extension Human Subjects Advisory Committee (EHSAC) will be considered to be *provisionally* certified and retain their eligibility status as investigators for human subject's research.

Similarly, individuals who have been designated as principal investigators or key project personnel on National Institutes of Health (NIH) grant applications *and* have been certified as having obtained training in the conduct of human subjects research by Purdue University prior to June 30, 2004 will be considered to be *provisionally* certified as PIs or key project personnel for human subjects research.

However, on January 31, 2006, the *provisional* education certification status of each of the above groups will expire *unless* these individuals have completed and passed the required Collaborative IRB Training Initiative (CITI) Basic Course for Investigators and Key Personnel with an overall passing score of 80%. See the CITI website (<http://www.citiprogram.org>) for specific information on which modules must be completed to meet Purdue's institutional requirements.

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Certification of New Principal Investigators

All Purdue employees serving as principal investigators and IU faculty at IPFW must be *certified* as educated in the conduct of human subjects research. Protocol applications submitted to a Purdue Institutional Review Board, or any of its designees, will not be approved or determined exempt until the principal investigator has fulfilled both of the following requirements:

1. In order to learn about the specific processes, procedures and review of human subjects research at Purdue University, investigators must either attend a workshop on Conducting Human Subjects Research at Purdue or complete training via an on-line version of the workshop when it is made available. The HRPP staff will work with representatives from the regional campuses and EHSAC staff to provide equivalent workshops to their faculty and staff. However, Purdue Pharmacy Practice investigators based at IUPUI who exclusively submit protocols to one of the IUPUI's IRBs *do not* need to attend this workshop.
2. To facilitate understanding of the historical context, as well as the ethical and regulatory requirements of conducting human subject's research, investigators must complete the CITI online training program with an overall passing score of 80%. See the CITI website (<http://www.citiprogram.org>) for specific information on which modules must be completed to meet Purdue's institutional requirements.
 - a. Principal investigators who conduct non-exempt research must complete the CITI Basic Course for Investigators and Key Personnel; either the learner group for Social Behavioral Research or the learner group for Biomedical Research, whichever is most appropriate.
 - b. Principal investigators who conduct **ONLY** exempt research as designated by the IRB must complete either the CITI Basic Course as described above or the learner group for Exempt Research. Please note, if an investigator chooses to take the Exempt Research training, should they at some point conduct non-exempt research, they will need to complete the CITI Basic Course as described in item a. above.

Principal Investigators are responsible for overseeing the training of all research team members including key personnel, non-key personnel and research personnel who work with identifiable, private information. The principal investigator must maintain records of training for these research personnel and make such records available for inspection at the request of the HRPP or the IRB. Such records may be in the form of a copy of the research team member's certification or an email from the HRPP verifying completion of the training.

Certification of Cooperative Extension Service Extension Educators

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Cooperative Extension Service Extension Educators must complete a combination of face-to-face training and online CITI training. Extension Educators must contact the Director of Extension or the EHSAC Coordinator for specific training dates and requirements.

Certification of Key Personnel

In order to be certified, Key Personnel must complete the CITI online training program Basic Course for Investigators and Key Personnel; either the learner group for Social Behavioral Research or the learner group for Biomedical Research, whichever is most appropriate, with an overall passing score of 80%. See the CITI website (<http://www.citiprogram.org>) for specific information on which modules must be completed to meet Purdue's institutional requirements. Attendance at a workshop on Conducting Human Subjects Research at Purdue, although encouraged, is not required. The required CITI training must be completed before a protocol application on which key personnel are named will be approved.

Certification of Non-Key Personnel

In order to be certified, Non-Key Personnel must complete the CITI online training learner group for Non-Key Personnel with an overall passing score of 80%. See the CITI website (<http://www.citiprogram.org>) for specific information on which modules must be completed to meet Purdue's Institutional requirements. The required CITI training must be completed before engaging in any research activities.

Certification of Personnel Who Conduct ONLY Exempt Research

Research personnel whose participation in the conduct of human subjects research is limited to research that qualifies for exemption must complete the CITI online training program learner group for Exempt Research with an overall passing score of 80%. See the CITI website (<http://www.citiprogram.org>) for specific information on which modules must be completed to meet Purdue's institutional requirements. The required CITI training must be completed before engaging in any research activities. Please note, if a research team member chooses to take the Exempt Research training, should they at some point participate in the conduct of non-exempt research, they will need to complete the CITI Basic Course as described for either key personnel or non-key personnel depending on their role in the research project prior to obtaining approval.

Continuing Education Requirement

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In order to maintain or renew certification to engage in human subjects research under the auspices of Purdue University, all investigators and key personnel must complete an online *CITI Refresher Course* with a passing score of 80%. See the CITI website (<http://www.citiprogram.org>) for specific information on which refresher course modules must be completed to meet Purdue's institutional requirements. The refresher course may be taken as frequently as CITI allows but no later than five (5) years after the investigator's initial successful completion of the CITI online training. If there is a lapse in an investigator's certification, he or she must complete the entire basic training course to become re-certified.

Principal investigators, key personnel and other research personnel who have been certified will always be welcome and encouraged to attend the workshop on Conducting Human Subjects Research at Purdue at any time, but will not be required to attend a session for purposes of maintaining or renewing their certification to conduct human subject's research. Principal investigators and key personnel will be notified of changes in regulations, HRPP procedures or Purdue policies using a variety of appropriate information dissemination strategies.

Contacts

Subject	Contact	Telephone
All questions	Human Protection Administrator, Office of Research Administration	(765) 494-6840

Definitions

Certification	Institutional verification through documentation that an individual has received education and/or training in the conduct of human subject's research and meet institutional requirements.
Consultant	An individual providing professional or expert assistance in the conduct of a research project.
Human Subject or Human Participant	These terms are used interchangeably. Under federal regulations, human subjects are living individuals about whom a researcher obtains data either (1) through intervention or interaction with the individual or (2) in the form of identifiable private information.

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Key Personnel	Members of a research team who contribute in a substantive way to the scientific or scholarly development, execution, or interpretation of a project.
Non-Key Personnel	Non-Key Personnel are research personnel who either interact with human subjects or access identifiable, private information but are not key personnel in the sense that they do not contribute in a substantive way to the scientific or scholarly development or execution of a project. For example, such personnel may assist in collecting data, but are always under supervision of the principal investigator and/or key personnel and do not act independently in the execution of the research project.
Principal Investigator (PI)	The scientist or scholar with primary responsibility for the integrity, design, conduct, and analysis of a research project that is eligible to serve as such at Purdue University (see VPR Policy I.1.1 Eligibility to Serve as a Principal Investigator for Research Involving Human Subjects).
Research	A systematic investigation, including testing and evaluation, designed to develop or contribute to generalizable knowledge or a larger body of discipline-specific knowledge. The IRB may determine an activity to be research regardless of the source of support and regardless of whether the activity is classified as research by other entities.