

Education Policy
For Investigators and
Key Project Personnel
Conducting Human Subjects
Research

VPR POLICY I.1.2

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: n/a
Most Recently Revised: May 21, 2004

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 wish to participate in the conduct of 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 comprise Purdue University's Human Research Participants' Protection Program (HRPPP). To document the necessary familiarity and understanding, all Purdue principal investigators, extension educator investigators, and key project personnel, including graduate 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 one of their designated subcommittees. The process by which an investigator becomes certified is described under the Procedures section.

This education policy applies to all Purdue University principal investigators, extension educator investigators, and key project personnel, including graduate students, who participate in research involving human subjects that is reviewed by a Purdue University Institutional Review Board or one of its designated subcommittees or by another institution's IRB under an inter-institutional cooperative agreement with 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 state and federal statutes and regulations 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.

Education Policy
For Investigators and
Key Project Personnel
Conducting Human Subjects Research

VPR POLICY I.1.2

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: n/a
Most Recently Revised: May 21, 2004

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 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 subjects 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 subjects research, Purdue investigators in the Department of Pharmacy Practice, based at IUPUI, must submit their human subjects 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 subjects 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 County or Field Extension staff 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.

There are no other exceptions.

Education Policy
For Investigators and
Key Project Personnel
Conducting Human Subjects Research

VPR POLICY I.1.2

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: n/a
Most Recently Revised: May 21, 2004

Who Should Know This Policy

Provost
Chancellors
Vice Presidents and Vice Provosts
Deans and Associate Deans
Department Heads and Directors
Principal Investigators

Faculty
Administrative and Professional Staff
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 Field 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 subjects 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 December 31, 2005, 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) training in the conduct of human subjects research (as described in the following section).

Education Policy
For Investigators and
Key Project Personnel
Conducting Human Subjects Research

VPR POLICY I.1.2

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: n/a
Most Recently Revised: May 21, 2004

Certification of New Principal Investigators and Key Project Personnel,
Including Graduate Students

On and after July 1, 2004, all Purdue employees serving as principal investigators and key personnel, graduate students serving as key personnel and IU faculty at IPFW not previously certified as educated in the conduct of human subjects research at Purdue must become *certified*. New human subject research applications and protocols submitted to a Purdue Institutional Review Board, or any of its designated review subcommittees, will not be approved or determined exempt until the principal investigator and all key personnel, including graduate students, have 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, individuals wishing to be certified must attend a Purdue Human Research Participants Protection Program (HRPPP) “Nuts and Bolts” Workshop on Conducting Human Subjects Research at Purdue held on or after July 1, 2004. The HRPPP 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.

AND,

2. To facilitate understanding of the historical context, as well as the ethical and regulatory requirements of conducting human subjects research, individuals wishing to be certified 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. Cooperative Extension Service Field Extension Educators must complete a combination of face-to-face training and online CITI training. Field Extension Educators must contact the Director of Extension or the EHSAC Coordinator for specific training dates and requirements.

As stated above, all investigators and key project personnel who had been *provisionally* certified as of June 30, 2004 must complete the online CITI training requirement (see #2 above) on or before December 31, 2005.

Continuing Education Requirement

In order to maintain or renew certification to engage in human subjects research under the auspices of Purdue University, all investigators and key project personnel, including graduate students, must complete the online *CITI Refresher Course* with a passing score

Education Policy
For Investigators and
Key Project Personnel
Conducting Human Subjects Research

VPR POLICY I.1.2

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: n/a
Most Recently Revised: May 21, 2004

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 must be taken and passed within five years of the investigator's initial successful completion of the CITI online training however, at least three years must have elapsed from the initial certification. 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 and key project personnel, who have been certified, will always be welcome and encouraged to attend the "Nuts and Bolts" Workshop at anytime, but will not be required to attend a session for purposes of maintaining or renewing their certification to conduct human subjects research. Principal investigators and key project personnel will be notified of changes in regulations or Purdue policies and procedures using a variety of appropriate information dissemination strategies.

Contacts

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

Definitions

| | |
|-----------------------|--|
| Certification | Institutional verification through documentation that an individual has received education and/or training in the conduct of human subjects research and meet institutional requirements. |
| Key Project Personnel | Members of a research team who contribute in a substantive way to the scientific development or execution of a project. This includes the principal investigator and any permanent staff devoting a significant amount of their effort to a single project or the conduct of human subjects research overall. In addition, graduate students engaged in a human subjects research project shall be considered as key project personnel and complete the certification requirements as part of their graduate studies. |

Education Policy
For Investigators and
Key Project Personnel
Conducting Human Subjects Research

VPR POLICY I.1.2

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: n/a
Most Recently Revised: May 21, 2004

| | |
|------------------------------------|--|
| Human Subject or Human Participant | These terms are used interchangeably. Individuals who are the subject of study in a research project. 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. |
|------------------------------------|--|

| | |
|-----------------------------|---|
| 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. |
|----------|--|