Institutional Review Board (IRB)
Human Subjects Protection Office
Penn State College of Medicine | Penn State Milton S. Hershey Medical Center
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HUMAN RESEARCH PROTECTION EDUCATION REQUIREMENTS

Penn State Hershey requires key personnel* involved in the conduct of human participant research, as defined by the federal regulations 45 CFR 46 and 21 CFR 50 & 56, to complete education in the protection of human research subjects, including continuing education every 3 years. The requirement for basic human research protection education was implemented in 2000, and required continuing education began in 2008. Effective July 1, 2011, an additional good clinical practice course is required for key personnel of research that is regulated by the Food and Drug Administration (FDA).

The principal investigator is responsible for ensuring that he/she and all key research personnel successfully complete the educational requirements.

Key Research Personnel:

*Key Research Personnel are individuals who (1) are involved in the design and/or conduct of the research, (2) have access to human participants, and/or (3) have access to confidential and identifying information. This includes principal investigators, co-investigators (sub-investigators), research nurses, study/project coordinators, associates/assistants, students, advisors and other support staff or persons assisting with the research.

The educational requirements must be met by key research personnel for all types of human research:

- convened, facilitated or expedited categories, and
- exempt research activities.

Undergraduate or graduate students serving as first time principal investigators are also expected to have an advisor experienced in human participant research and familiar with institutional requirements.

Current Certification:

Certification of current** human research protection education for all investigators and key research personnel is verified by the Human Subjects Protection Office (HSPO) at the time of each new submission, and a submission will not be accepted until the educational requirements are met. If the educational requirements are incomplete or not current for any investigator or key personnel, the submission will be returned with instructions regarding what is needed and to re-submit after the requirements have been addressed.

**All investigators whose certification for a required course will be 3 years old <u>within 30 days from the date of submission to the IRB</u> will be required to update their course certification for continuing education, according to the Penn State Hershey educational requirements outlined below.

Curriculum Requirements:

Penn State Hershey requires completion of the on-line educational curriculum maintained for Penn State Univ. – Hershey on the Collaborative Institutional Training Initiative (CITI) web site. The required courses and continuing education requirements are outlined as follows.

Additional educational requirements will apply for federally funded research, such as the National Institutes of Health (NIH) requirements, when applicable.

CITI Course: Protection of Human Research Subjects – Biomedical course

Initial requirement

This is the core requirement for all key personnel who are Penn State Hershey faculty, staff and students involved in conducting human research. The course covers the conduct of human participant research, including clinical studies, biomedical research, and behavioral or social science research.

Continuing education requirement

Continuing education renewal for this course is due every 3 years and may be fulfilled by completing the Refresher course or repeating the initial course.

Substitutions:

- Previous CITI Course Work -
  Individuals with CITI Protection of Human Research Subjects course work from another institution within the last 3 years may complete affiliation steps in CITI to apply those courses toward fulfilling the local requirement, or provide a certificate listing comparable CITI modules completed.
- Other Penn State Campuses/Colleges faculty, staff, students serving as key personnel -
  Applicable individuals may substitute the current course (within last 3 years) of the University Park Office for Research Protections (ORP) required human subject research training, or an ORP-accepted substitute, for the initial and continuing human subject protection education requirement.
- Non-affiliated key personnel (not employed or a student of a PSU or Penn State Hershey entity)
  May substitute human research protection training taken within the last 3 years at the institution where he/she is currently employed, or from the National Institutes of Health, for the initial and continuing human subject protection training.

Good Clinical Practice and ICH (GCP) Course

Effective July 1, 2011, the Good Clinical Practice Course is required for key personnel of research that is regulated by the Food and Drug Administration (FDA). The current GCP requirement must be met for all key research personnel on FDA-regulated studies, along with the human research protection course, before a new submission or modification to add personnel will be accepted for review by the Institutional Review Board (IRB).

GCP Initial requirement

This additional course is required for all key personnel involved with human research regulated by the Food and Drug Administration (FDA). The course covers requirements for FDA-regulated research, including the specific obligations and reporting requirements for investigator-initiated research and sponsor-investigators of studies involving investigational new drugs or devices (IND/IDE).

GCP continuation education requirement

Continuing education renewal for the GCP course is due every 3 years and may be fulfilled by completing the Refresher course or repeating the initial course.

Substitutions:

- Sponsors' specific GCP courses will not meet this institutional requirement.
- Individuals with completed CITI GCP coursework within the last 3 years from another institution may complete affiliation steps in CITI to apply those courses toward fulfilling the local requirement, or provide a current CITI GCP certificate.

Effective Date: January 1, 2012
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Most recent changes:

- November 29, 2011 – Effective January 1, 2012 the educational requirements apply to all categories of research that meet the definition of human subjects research, including exempt activities.
- May 6, 2011 – Included description of the Good Clinical Practice and ICH course (GCP) requirement for key personnel on FDA-regulated research, effective July 1, 2011, implemented by the Vice Dean for Research to address educational needs identified in an internal COM audit.

Revision History (and effective dates):

- May 6, 2011 – Revision History added.
- January 1, 2011