



HUMAN SUBJECT RESEARCH – TRAINING & GUIDANCE

All students, faculty and staff conducting research with human subjects must complete specific training before initiating research activities. The training guidelines listed below vary according to each individual's role in conducting the research as well as the nature of the research being performed. Therefore, these should be considered as guidelines to both required and optional modules. At a minimum, the IRB requires each investigator to complete two courses, which vary depending on the background and interests of the researcher. Three researcher 'learner groups' exist: (a) biomedical researchers; (b) social & behavioral researchers; (c) undergraduate students. There are two courses that must be completed within each learner group. The 'Basic' course covers the protection of human subjects; the 'RCR' Course covers the responsible conduct of research'. Individuals who have previously completed CITI modules for another institutional training program may be able to transfer those credits to our site if those modules were completed within the prior 12 months. Similarly, individuals seeking to meet certification for other entities (e.g., VA Medical Centers) may be able to transfer Pitt CITI credits to those programs.

<u>Collaborative Institutional Training Institute (CITI) Program</u>	
Courses	Explanation of requirement
CITI Basic Human Subjects Protection Training Program CITI Responsible Conduct of Research (RCR) Training Program	Required for all individuals conducting human subject research Re-certification will be required every 3 years and a CITI 'Refresher Course' will be available at that time
Good Clinical Practice (GCP) It is the responsibility of the Principal Investigator to ensure that key personnel complete this course.	Required for all key personnel who are involved in the conduct of FDA-regulated studies before beginning an FDA-regulated study. 'Key personnel' include the Principal Investigator and any sub- or co-investigators or study coordinators who have more than minimal involvement with the conduct of the research (i.e., they perform research procedures or evaluations and contribute significantly to the collection of the research data) and/or who have more than minimal contact with research subjects or with their identifiable study records or specimens.

Guidance for accessing CITI: [CITI Instruction Sheet](#)

General IRB inquires: Email askirb@pitt.edu

OSIRIS or CITI inquires: Email irb@pitt.edu

Note: CME/CEU credits for the courses are available for a nominal fee from CITI. Detailed information is available from the CITI Main Menu page.

Additional training courses, not part of CITI, may be needed to access UPMC Medical Records (e.g., the HIPAA Training Module) or to meet University/UPMC requirements for COI Training when a Significant Financial Conflict of Interest is determined by responses to the Pitt/UPMC COI Superform. These courses are found on the [Internet-Based Studies in Education and Research](#) (ISER) website for Pitt researchers and the [My HUB](#) website for UPMC researchers.

Additional Training Modules That May Be Required, Depending on Circumstances	
Internet-Based Studies in Education and Research ISER Modules	
Modules	Explanation of Requirements
Bloodborne Pathogens Training Staff and students must complete initial training ‘live.’ Annual re-training can be via this module.	Required for all University employees with occupational exposure to human blood, body fluids or tissues, pathogenic bacteria or viruses, and other potentially infectious materials For more information contact Environmental Health and Safety
Chemical Hygiene Training Re-certification required every 3 years	Required for all faculty and staff potentially exposed to chemicals in a laboratory or research environment during their assigned job functions. Note: For investigators employing animals in research, completion of the Use of Laboratory Animals in Research and Education module fulfills this requirement. For more information contact Environmental Health and Safety
HIPAA Researchers Privacy Requirements	Required for any member of the research team who views identifiable protected health information (e.g., medical records) must complete this module Note: If you are a UPMC employee or if you have access to protected health information at UPMC, there are additional modules that may be required.
Conflict of Interest	May be required by the Conflict of Interest Committee as part of the management plan
Human Embryonic and Fetal Stem Cell Research	Required for all research involving fetal tissue and human embryonic stem cells. Also required for certain types of human non-embryonic stem cell research – please refer to the hSCRO policy at http://www.rcco.pitt.edu/hscro/
Research with Children	Recommended if the research involves participants under the age of 18
Research Integrity	Required for individuals conducting research who are not required to take the CITI modules
<div>  Go to the Module Listings and click on Responsible Conduct of Research for a complete list of modules If you are an UPMC employee, additional modules may be required by UPMC </div>	