Overview

The following document outlines research training requirements for individuals who conduct research at the University of Pittsburgh, including faculty, staff, and students. The University recognizes that academic research is substantively, procedurally, and administratively complex. The purpose of this training is not only to satisfy government and University of Pittsburgh policy requirements, but to enhance research activities at all stages. Our goal is to make training understandable and meaningful, while providing it as efficiently as possible. Constructive criticism about the training program is always welcome, and should be directed to rcco@pitt.edu.

Who must complete the training?

Anyone conducting research* at the University of Pittsburgh is required to complete training prior to beginning the project, regardless of funding source. Training requirements vary based on the nature of the research. While there are obvious differences in training requirements for those performing animal subject research and human subject research, there are requirements that may be applicable to all research. Those requirements that cross domains are listed separately and should be reviewed closely.

* For those in the Kenneth P. Dietrich School of Arts and Sciences, scholarly activities that meet the threshold to be considered research (primarily natural and social sciences) are when emphasis is on testing, verification, and use of empirical data.

Web-based Training

The University of Pittsburgh offers several training resources. The two primary online training portals are:

- ### Collaborative Institutional Training Initiative (CITI)

  The CITI training program is a leading global provider of online research ethics education. Many of the CITI courses qualify for continuing education credits (CMEs/CEUs) which can be purchased directly from CITI.

  To access the CITI training, individuals must log into the Pitt CITI access portal using a Pitt HSConnect username/password as it provides a database for University Departments and other systems to verify CITI training. Detailed instructions are displayed on the Pitt CITI Portal login page at www.citi.pitt.edu. Questions should be directed to citi@pitt.edu.

  Individuals can go to www.hsconnect.pitt.edu to create a new HSConnect account or to update their profile. It is important not to create duplicate accounts. The HSConnect support team can be reached by calling 412-648-2222.

All online training is logged and a record of training can be accessed on the HSConnect database by the trainee or School/Department Administrators as needed. The online applications for animal studies (ARO) includes a display of training records for CITI. The online application for human subjects research (OSIRIS) includes a display of CITI training records.

Community Partner Research Ethics Training (CPRET)

The Community Partner Research Ethics Training (CPRET) and Certification is intended for community partners that are non-university employees who actively participate in research with human subjects (but will not be listed as a member of the research team in the IRB application). This course provides them with the opportunity to learn about conducting research that is ethical and safe. Email partners@hs.pitt.edu for more information.

Required Training

All Investigators

Responsible Conduct of Research (RCR)

All individuals involved in research are **required** to complete the CITI Responsible Conduct of Research course before participating in research activities. This requirement also applies to faculty mentors listed in the IRB application who are responsible for the conduct of research for their students.
Re-certification is required every 4 years.

- Responsible Conduct of Research (CITI)

Trainees who receive National Science Foundation (NSF), National Institute of Health (NIH) or other support from a training grant may be required to complete additional, in person, discussion-based RCR training. The University of Pittsburgh Clinical & Translational Science Institute (CTSI) holds RCR Center workshops which may meet these requirements. If you have any questions about this additional requirement, contact Teri Reiche at tmr75@pitt.edu.

Conflict of Interest (COI)

The University of Pittsburgh COI Policy for Research RI01 **requires** all investigators who are externally funded (regardless of funding source) to complete the CITI COI course. Regardless of sponsor, the release of funding for any award is contingent upon all investigators on the project having completed the CITI COI course within four years of when the **award is executed and before initiating research.**
Training must be renewed every four years.

- Conflict of Interest (CITI)

NOTE: **an investigator includes any individual, regardless of title or position, who is (or may be perceived to be) independently responsible for or significantly influences, the design, conduct or reporting of the research.**

The Principal Investigator (PI) is responsible for identifying the individuals who meet this definition (see guidance below). When funding is awarded, the PI must provide the Office of Sponsored Programs with a completed CITI COI Training Table, which is a list of the individuals who meet this definition and the date on which they completed the CITI COI course. The PI must maintain copies of the course completion certificates for all investigators and update the list as personnel changes occur.

Individuals who conduct research without any external funding are required to complete the CITI COI course **only when** they 1) disclose outside financial interests on their conflict disclosure form in MyDisclosures or 2) have been directed by their Department Chair or equivalent supervisor to complete the CITI COI course.

Individuals who conducted research at the University may no longer be affiliated with the University when the results of the research are published. These individuals are not required to complete or renew the CITI COI course at the time of publication.

Guidance: Who is an investigator?

This is a guidance tool and may not capture all scenarios and all descriptions of an investigator. When in doubt, an individual should complete the CITI COI course.

1. The Principal Investigator, any co-investigators and any other individuals who are independently responsible for or who have or who may acquire authority from the PI to significantly influence the design, conduct, outcome, or reporting of the research, data acquisition, methods and analysis of the research;
2. Any co-investigator and any other individual who may be a co-author on manuscripts or presentation of the research findings, including any students who meet this definition;
3. Senior/Key Personnel who are identified on a grant, funding application or report as contributors to the research regardless of whether they receive salary support;
4. Collaborators and consultants at the University of Pittsburgh who are independently responsible for or significantly influence the design, conduct, outcome or reporting of the research, data acquisition, or methods and analysis of the research;
5. Subrecipients, collaborators and consultants outside of the University of Pittsburgh who are performing PHS-funded research on behalf of Pitt who are independently responsible for or who significantly influence the design, conduct, outcome or reporting of the research, data acquisition, or methods and analysis of the research; The University of Pittsburgh will accept COI training from outside Institutions that have PHS-compliant policies. If the outside institution does not have a PHS-compliant COI policy, the Investigator must complete Pitt's CITI COI training module.
6. Postdoctoral students and clinical fellows may be considered investigators depending on their ability to directly and significantly influence the design, conduct, outcome or reporting of research. Whether such individuals are investigators should be determined by the PI on a case by case basis.

The following are not usually considered Investigators:

1. Consultants who provide a "fee for service" only and do not conduct the research.
2. Administrators or individuals who perform routine or supportive tasks related to the research.

More information is available on the Pitt COI office website at http://www.coi.pitt.edu.

Animal Research

Use and Care of Laboratory Animals

Anyone performing animal research, including faculty, staff, and students are **required** to have completed appropriate training prior to beginning the project, regardless of funding source. Note that after completion of training, the individual must be added to an active protocol approved by the Institutional Animal Care and use Committee (IACUC) prior to commencing animal research.

All individuals engaged in animal research must complete the ISER Use and Care of Laboratory Animals module before being added to an IACUC protocol and interacting with any animals. ***Re-certification is required every 4 years.***

- Use of Laboratory Animals in Research and Education (ISER)

Animal Research: Species Specific

All individuals engaged in animal research are **required** to complete relevant animal modules available on the ISER or CITI website. See the IACUC training page (http://www.iacuc.pitt.edu/training) for more information about the modules related to research on each species. ***Re-certification is required every 4 years.***

- Animal Species Specific Modules
- Animal Specific Courses (limited modules) (CITI)
    - Working with Amphibians in research setting
    - Working with Guinea Pigs in research setting
    - Working with Hamsters in research setting

All individuals engaged in animal research are **required** to complete relevant animal modules available on the ISER or CITI website. See the IACUC training page for more information about the modules related to research on each species. ***Re-certification is required every 4 years.***

Human Subject Research

Human Subject Protections

Any member of the research team interacting or intervening with human subjects or their data, including faculty, staff, and students are **required** to have completed appropriate training prior to beginning the project. Members of the study team whose responsibilities are limited to the entry of de-identified data are required at a minimum to complete Responsible Conduct of Research.

All individuals, as defined above, who are engaged in human subject research are **required** to have completed **one** of the human subjects' research courses listed below based on their primary area of research. ***Re-certification is required every 4 years.***

- Human Subjects Research (CITI)
    - Biomedical course
    - Social-Behavioral-Educational course

Research Specific Training

Biosafety and Biosecurity

Institutional Biosafety Committee (IBC)

Biosafety – NIH Guidelines (*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*) training is **required** for all personnel using materials or agents that contain recombinant and/or synthetic nucleic acid molecules (DNA, RNA, or other genetic material) at the University of Pittsburgh and affiliated institutions. Training for investigators and research staff includes safety considerations in the principles of construction or handling of IBC-oversight materials, and regulatory requirements.

Note that if you perform research activities such as: to amplify or clone plasmids in bacterial cultures, work with viral vectors, perform experiments with siRNA *in vivo* or in *vitro*, conduct clinical trials using agents that contain recombinant DNA or segments of genetic material, or maintain a breeding or crossing-breeding colony of rodents, then these activities must be registered with the Institutional Biosafety Committee Office, as they fall under experiments in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. Additional training and consultation is offered by the staff of the Institutional Biosafety Office (IBC Office). Visit the Institutional Biosafety Committee (IBC) website (http://www.ibc.pitt.edu/)for more information.

Individuals are **required** to complete the NIH Guidelines course on the ISER website. ***No recertification required.***

- Biosafety-NIH Guidelines (ISER)

Clinical Research Coordinator

This **optional** course is highly recommended for new study coordinators as it provides an overview of the role and responsibilities of a study coordinator. It may also be used a refresher course for experienced coordinators. **No re-certification required.**

- Clinical Research Coordinator (CITI)

Clinical Trial Billing Compliance

This **optional** course is relevant to individuals whose responsibility includes billing for research procedures. **No re-certification required.**

- Clinical Trial Billing Compliance (CITI)

Environmental Health & Safety (EHS)

The University of Pittsburgh Department of Environmental Health & Safety (EHS) provides support and training to researchers and personnel, including those involved in work with animal and/or human subjects. There are multiple regulations, guidelines, and best practices that contain training requirements for employers. The department is proactive in implementing training programs to meet these requirements, as well as to supplement and enhance environmental, health, and safety activities at the University of Pittsburgh. EHS provides a variety of training options including both live and online training options to accommodate the needs of the University community.

Safety training requirements vary according to the research conducted or work directed by the investigator.

- **Bloodborne pathogens training is required annually** for all personnel with potential exposure to human blood, human body fluids or potentially infectious material in a research or teaching environment, in accordance with OSHA regulations.

- **Chemical hygiene training is required every 3 years** for all personnel who handle laboratory chemicals.
- Training in the **Shipment of Dangerous Goods is required every 2 years** for all personnel that package certain materials for shipment or label such material for shipment. These fundamental safety training topics are available online through the ISER web-based training site, and through the EHS website. Additional live sessions of training courses are offered several times a month.

- Environmental Health and Safety (ISER)
  - Blood-borne Pathogen Training (ISER)
  - Chemical Hygiene Training (ISER)

- Live Training and Additional EHS-Sponsored Online Training Schedule
  - Shipment of Dangerous Goods
  - EHS website at http://www.ehs.pitt.edu/workplace/training.html

Export Controls

This **optional** course is highly recommended for individuals who work with or may be responsible for federally controlled devices, materials, or technologies. The U.S. Export Controls regulations aim at protecting the national security, economic interests and foreign policies of the United States. Export laws regulate the transfer, release, or disclosure of controlled items, technology, and software to foreign countries or to foreign persons and entities within the U.S. ***No re-certification required.***

- Export Controls (CITI)

Good Clinical Practice (GCP)

The University of Pittsburgh recognizes that GCP training is important for all researchers conducting "clinical trials" to ensure the protection of human subjects and the integrity and quality of our research. Therefore, all Investigators and research team members who are engaged in the conduct, oversight or management of clinical trials (as defined by the NIH) are **required** to complete the CITI GCP training course before they participate in any research activities. **The University has extended this requirement to all research studies that meet the definition of a clinical trial regardless of the funding source.**

It is the responsibility of the Principal Investigator to ensure that all members of the research team who meet this requirement (see guidance below) complete GCP training and maintain certification during the course of the study. As of January 1, 2017, the Institutional Review Board (IRB) will not approve a new "clinical trial" submission unless GCP training is complete. There are (2) GCP training courses available. If you currently participate in an FDA regulated clinical trial or plan to do so in the future, complete the FDA regulated GCP course. All others should complete the Behavioral or non-FDA regulated GCP course. ***Re-certification is required every 3 years.***

- Good Clinical Practice (CITI)
    - GCP for Clinical Trials Involving FDA regulated research
    - GCP for Clinical Trials Involving Behavioral or non-FDA regulated research

Guidance on who must complete GCP training:

Those required to take GCP training include those who:

1. Manage participant recruitment and enrollment, including obtaining consent
2. Perform research procedures or evaluations
3. Contribute significantly to the collection and recording of research data or
4. Contribute significantly to data management
5. Have more than minimal contact with the research subjects or their identifiable study records or specimens

Those not required to take GCP training include:

Hospital staff (including nurses, residents, fellows, or office staff) who provide ancillary or intermittent care but do not make a direct and significant contribution to the study or administrators or individuals who perform routine or supportive tasks related to the research.

* The NIH defines a clinical trial as: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html#sthash.U12c4BnW.dpuf

Humanitarian Use Device (HUD)

UPMC **requires** this course be completed for all research or clinical use of HUDs at any of their facilities. ***No re-certification required.***

- Humanitarian Use Device (CITI)

Human Stem Cell Research

Human Stem Cell Oversight Committee (hSCRO)

The University of Pittsburgh's hSCRO Committee is to ensure that all federal and Commonwealth of Pennsylvania regulations governing the conduct of human embryonic stem cell research are met and that other human stem cell research is conducted in accordance with the general principles expressed in the National Academies' *Guidelines for Human Embryonic Stem Cell Research*, with the policies and procedures adopted by the hSCRO Committee, and with other relevant University of Pittsburgh research policies.

Investigators are **required** to complete the CITI Human Stem Cell course in conjunction with a submission of a research protocol to the hSCRO. Visit the Human Stem Cell Research Oversight Committee (hSCRO) website (http://www.ibc.pitt.edu/hscro) for more information. ***No recertification required.***

- Human Stem Cell Researchers (CITI)

International Research

This course is **required** for all members of the research team engaged in human subject research outside the United States. ***Re-certification is required every 4 years.***

- International Research (CITI)

Privacy & Information Security for Researchers

Anybody who encounters protected health information (PHI) for research purposes is **required** to complete the CITI Health Privacy and Information Security training. ***Re-certification is required every 4 years.***

- Health Privacy (CITI)
- Information Security (CITI)

This training is in addition to any clinical HIPAA training completed through UPMC or the Pitt Clinical HIPAA training on ISER.

Radiation Safety

Radiation safety training is **required** for all personnel using radioactive materials or working with radiation producing equipment at the University of Pittsburgh and affiliated institutions. Training for radiation workers includes instruction in the basic principles of radiation protection and the applicable policies, procedures, and regulatory requirements. Personnel are required to attend training sessions offered by the Radiation Safety Office.

Radiation safety trainings are available in three application categories:

1) general isotopes;

2) gamma and x-ray irradiators; and

3) analytical and research x-rays.

The initial training sessions, available monthly or as needed, are conducted by staff of the Radiation Safety Office. Registrations of the training sessions are made through the Radiation Safety Office

website. ***Refresher trainings, in-person or online, are required every 3 years.*** Visit the Radiation Safety Office (http://www.radsafe.pitt.edu/) for more information.

Research with Children

The Children's Hospital of Pittsburgh of UPMC **requires** this module be completed by all members of the research team participating in research activities conducted at their facility. ***Re-certification is required every 4 years.***

- Research with Children (CITI)