	UNIVERSITY RESEARCH POLICY: Researcher Training			
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Policy Statement

This policy describes the policy and procedures for the training of personnel for research involving human subjects.

Reason for Policy

This policy helps ensure that human subjects research meets all regulatory requirements.

Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research; the IRB committee members and chairs; Research Integrity office staff.

Who Should Read This Policy

- Faculty, staff, and students of the university engaged in human subjects research subject to IRB review and oversight
- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff

Responsibilities

Responsible Party	List of Responsibilities
Designated reviewers	Apply this policy when conducting reviews of IRB applications.
Lehigh University faculty, staff, and students submitting human subjects research for IRB review	Read, understand, and follow this policy when preparing applications for submission to the IRB. Read, understand, and follow this policy when conducting human subjects research.
Research Integrity office staff	Process IRB reviews and apply this policy when research involves humans as research subjects.


Principles

Lehigh University has adopted the federal standards for the protection of human subjects in research. The federal standards require all individuals involved in the conduct of human subjects' research to complete human subjects' protection training prior to any interactions / interventions with human subjects or their identifiable private information.

Procedures

Initial Screening

Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether this policy applies to the study.

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Human Subjects Protection Training

Any individual working with human subjects in research must complete an online tutorial through the CITI platform (<https://www.citiprogram.org>). The tutorial course is titled “Social & Behavioral Research – Basic Course.” Instructions for signing up for CITI and accessing the online tutorial can be found [here](#).

Individuals should save a copy of the course completion certificate and submit it with his or her human subjects protocol or shortly thereafter. The tutorial must be completed before the study/protocol can be approved. It is recommended that the tutorial be completed before submitting the study package through IRBNet. The completion certificate is issued with an expiration date; however, individuals are not required to update expired completion certificates prior to submission.

Faculty are only required to submit this training once; students will need to submit a copy of their completion certificate with every new protocol. Individuals who have previously completed equivalent training in human research participant protection (ex: NIH PHRP course) may instead submit evidence of past training.

GCP Training for NIH-supported Clinical Trials

All personnel on NIH-supported projects that meet the definition of a “clinical trial” are also required to complete the Society of Behavioral Medicine’s “Good Clinical Practice for Social and Behavioral Research eLearning Course”. Training must be refreshed every three years. This training is designed for investigators involved in behavioral clinical trials. Lehigh University researchers involved in NIH-supported biomedical clinical trials must contact the Research Integrity office for assistance identifying suitable training.

The SBM eLearning course can be found at: <https://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course>

Web Address For This Policy

[Lehigh University IRB website](#) (IRB Standard Operating Procedures and Policies)

Related Resources

University Policies and Documents
Lehigh University IRB Glossary
CITI Human Subjects Protection Training Tutorial

Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Senior Research Integrity Specialist	610-758-2871	https://research.cc.lehigh.edu/contact-us-0

Policy Updates

Date	Update
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Updated training instructions to reflect the discontinuation of the NIH PHRP online training course.