

 Office of Research Integrity - Human Subjects			SOP #: ORI(HS)-4.05
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Approved By: ORI Executive Director	*Signature on file	Date:	Date First Effective: May 9, 2016
Approved by: Biomedical Chair	*Signature on file	Date:	
Approved by: Social Behavioral Chair	*Signature on file	Date:	Revision Date:

SOP 4.05 – Education and Training: Principal Investigators and Research Team Members

1. Objective

The purpose of this SOP is to describe training requirements and review considerations for all research team members, including the principal investigator (PI), involved in conducting research and interacting with human subjects, and/or their private identifiable data.

2. General Description

In order to promote ethical and scientifically-sound research, and to adequately protect human subjects, all researchers interacting with human subjects, and/or their identifiable private information must complete and maintain the minimum required training in order to meet organizational requirements and comply with all applicable federal, state, and local regulations. This requirement applies to exempt and non-exempt research alike.

The primary method for satisfying minimum training requirements is to take online education courses offered by the Collaborative IRB Training Initiative (CITI). The CITI Human Subjects Research Course consists of basic online courses prepared for researchers conducting social/behavioral or biomedical research. Additional training or experience may be necessary, and is generally determined on a case by case basis with consideration to the specific study protocol.

3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/research team members, IRB Chair, IRB, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

All PIs and research team members are minimally required to complete CITI ethics training courses designated under either a social/behavioral, or biomedical track, and depending on whichever is most appropriate for the type of research being conducted. CITI training includes a review of the “Belmont Report.” PIs and research team members are additionally responsible for being familiar with any relevant professional standards unique to their field, and applicable University policies including the ‘UNLV Rules and Procedures for Conducting Human Subject Research.’ PIs and research team members are assessed for their experience relative to their research roles and the study procedures.

The PI should ensure that there is adequate training for all research team members and study staff participating in the conduct of the study. The investigator should ensure that research team members and staff:

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- are familiar with: the approved study protocol, and, when applicable, attributes of any investigational product(s) needed to perform assigned tasks,
- are competent to perform or have been trained to perform the tasks they are delegated,
- are informed of any changes during the study, and receive additional training as may be appropriate,
- when applicable, receive any study sponsor training and/or information (e.g. training materials) that is pertinent to their assigned role in the study.

Principal Investigators are ultimately responsible for the conduct of research. Principal Investigators may delegate research responsibility. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

Persons involved in the design and implementation of a research protocol, but that are not interacting with human subjects, and/or their private identifiable data do not have an immediate requirement to fulfill the training requirements discussed in this SOP, but should nevertheless be knowledgeable and adequately trained to perform their designated tasks.

4. Procedures

Required Training and Experience for Researchers

All UNLV researchers are required to complete the online training [Collaborative Institutional Training Initiative \(CITI\) Human Subjects Research Course](#). This includes PIs, student investigators, and research team members.

UNLV requires that researchers complete all modules appropriate for their type of research. Researchers focused on social and behavioral science must complete the CITI Social/Behavioral Research Course Modules. Researchers focused on biomedical science must complete the CITI Biomedical Research Course Modules. Researchers will be required to read the Belmont Report and the conflict of interest in human subjects research information as well. An accumulated CITI course score of at least 75% or better is required to successfully complete the course. A CITI certification must be current within the last five years at the time of study submission, or continuing review submission.

Where investigational products are involved in the research, researchers must evidence familiarity with the appropriate use of any investigational products as described in the protocol, current researcher brochure, product information materials, or any other information sources that may be provided by sponsors.

The IRB will not approve research involving human subjects until certification of completion of the required training is confirmed for all members of the research team.

Training Expiration & Renewal

The CITI user account notification system will alert users with an active account about an impending expiration. Researchers with an active CITI user account can log into the CITI website and view their current and past training. A CITI certification must be current within the last five years at the time of study submission, or continuing review submission.

Training Exceptions

When collaborating investigators, or subcontract recipients, are employed at external institutions that have requirements for human research protection training, the UNLV IRB generally accepts documentation that the external institution's training requirements have been met and are current. Collaborating investigators employed at external institutions that do not have requirements for human research protection training must

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comply with the stated training requirements, or provide evidence of current equivalent training. A copy of any such certification(s) must be provided with the other study documents and verified prior to study approval, or re-approval.

Transcribers & Transcriptionists

People hired, or brought on to a research team for the sole purpose of transcribing audio/video/medical data do not have to maintain a current CITI certification, though they must still be a named research team member in the approved protocol. A ‘Transcribers Confidentiality Agreement’ must be on file with the IRB application in place of, or in addition to current CITI certification.

5. References

Collaborative Institutional Training Initiative (CITI): www.citiprogram.org
AAHRPP Standard: I.I.D, III.2.A, Tip Sheet 11
ICH-GCP (E6)
Institutional Review Board Management and Function, Bankert & Amdur – Chapters: 8-12
<http://www.unlv.edu/research/ORI-HSR/training>
<http://www.hhs.gov/ohrp/policy/faq/index.html>