**Virginia Tech Human Research Protection Program**

**Human Research Protections Training Requirements**

**HRP-010** **DRAFT v1.6** **Effective Date: January 21, 2019**

## Purpose

The Researcher Training Requirements policy is updated in this SOP to meet Virginia Tech's obligation to the revised federal human participants research protections regulations at 45 CFR part 46 (also known as the "IRB regulations" and the "Common Rule"), which are in effect beginning January 21, 2019. To ensure that all investigators and research staff are consistently and thoroughly trained in the ethical conduct of human participant research, Virginia Tech requires that all members of the research team complete human participant research training before interacting with research participants, or collecting or handling human participant data. Principal investigators must ensure that all study personnel have the required training on file with the Virginia Tech Human Research Protection Program (HRPP) before submitting the protocol for IRB review.

## Policy

### Training Requirements

As of January 21, 2019, Virginia Tech requires new investigators and study personnel (including student researchers, post-doctoral fellows, researchers from other institutions, independent [non-University/contracted/community] researchers, and all study staff listed on an approved research protocol or later added to the project through an amendment) to complete the CITI Program (CITIprogram.org) *Human Subjects Research Basic Course* (either Biomedical and/or Social-Behavioral-Educational, depending on the focus of the research protocol). The *Biomedical* and/or *Social-Behavioral-Educational Refresher Course* is required every 3 years. The *Refresher Courses* are designed to provide updated or additional content and are not a repeat or duplication of the *Basic Course*.

### Continuing Education Credits

Participants can earn continuing education credits for completing this training requirement. See CE Certified Courses for additional information.

### Training Renewal

Completion of the *Human Subjects Research Basic Course* (or *Refresher Course*, if applicable) covers the training requirement for all human participant research conducted by the investigator or study personnel during the 3-year period. Additional training is not required for each protocol during the 3-year period.

Investigators and study personnel who have already completed the pre-2019 Virginia Tech IRB training requirement (as documented in the HRPP Protocol Management system) have until January 2021 to complete the CITI *Human Subjects Research Basic Course*.

Training Certificates

All researchers who interact with human research participants, or collect or handle data, must achieve at least an 80% score on each module. Each module quiz can be taken as many times as necessary to achieve an 80% score. Course scores are provided to the investigator and to the Virginia Tech HRPP through the online CITI portal when completed.

Transfer of CITI Certificate

Study personnel who have a current CITI *Human Subjects Research Basic Course* certificate (or *Refresher Course* certificate) from another institution do not need to re-take the training at Virginia Tech. Current certification will be sent directly to HRPP when the researcher affiliates with Virginia Tech using their CITI log in. Once affiliated with Virginia Tech, the certificate is provided directly to HRPP through the CITI online portal.

Clinical Trials

All investigators and research staff who are involved in the design, conduct, oversight, management, or reporting of clinical trials (as defined by the NIH) involving human participants are required to complete the CITI *Human Subjects Research Basic Course* and *Good Clinical Practice (GCP)* training.

FDA-Funded Research

If the research is funded by the U.S. Food and Drug Administration (FDA), regulations and guidance require additional training in GCP. Please visit FDA.gov for additional information on obtaining required training online or in-person.

Research with Medical Records

All investigators and research staff who directly access patient medical records or have access to a dataset that includes identifiable data from patient medical records are required to complete the CITI *Information Privacy and Security (IPS)* training. "Identifiable data" include any of the recognized HIPAA identifiers.

Principal Investigator's Responsibility

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with human research participants, or collect or handle human participant data have completed CITI human participant protection training before interacting with research participants, or handling or collecting data. This includes, but is not limited to team members (graduate students, undergraduate

students, etc.) who code recordings (e.g., video or audio recordings), observe research activities, and enter or analyze data.

Training Verification and Documentation

CITI maintains training certificates and scores in its archive. CITI training records are available upon log in. Investigators and study personnel are encouraged to print their module scores and completion certificates, and to note their training expiration date, by which the appropriate CITI *Refresher Course* must be completed.

A protocol will not be eligible for final submission in the Protocol Management system until all investigators and research staff have completed the *Human Subjects Research Basic Course* (or *Refresher Course*). Investigators or research staff who are unable to complete their training before protocol submission to the electronic system may be removed from the protocol and added at a later date following protocol approval though a protocol amendment once their training is complete.

Definitions and acronyms

CITI: Collaborative Institutional Training Initiative. An online research ethics training collaborative.

FDA: U.S. Food and Drug Administration

FWA: Federalwide Assurance. An agreement between an institution (Virginia Tech) and the federal government through which Virginia Tech commits to comply with the federal regulations governing research with human subjects.

GCP: Good Clinical Practice. A training course specific to clinical trials that describes ethical and scientific standards required to design, conduct, and report results from clinical trials.

HIPAA: Health Insurance Portability and Accountability Act of 1996. This law provides individuals with rights over their health information, including information about who is allowed access to and has accessed their medical record data.

HRPP: Human Research Protection Program. A program in the division of Scholarly Integrity and Research Compliance at Virginia Tech that guides researchers and supports the IRB through regulatory approvals.

IRB: Institutional Review Board. A federally mandated board of research peers to assess research protocols for ethical and regulatory compliance.

NIH: The National Institutes of Health. The principal federal agency for health research in the United States.

PI: Principal Investigator. The PI is responsible for ensuring that all co-investigators and study personnel complete and register their human research protections training.

## References

Office for Human Research Protections. 2017. Federalwide Assurance (FWA) for the Protection of Human Subjects. Department of Health and Human Services: Washington DC.

Collaborative Institutional Training Initiative (CITI) Program. 2018. CITIprogram.org

## Procedure

1. Navigate to CITIprogram.org
2. **For new CITI users**
    a. Sign in by clicking the "Log In" button and selecting "Log in through my institution" and selecting Virginia Polytechnic Institute & State University, OR register a new account and affiliate with Virginia Polytechnic Institute & State University in the "Select Your Organization Affiliation" section. Non-University/contracted/community researchers may affiliate to Virginia Tech at the time of new account creation. Please contact HRPP staff at IRB.vt.edu for assistance if needed.
    b. Navigate to the *Human Subjects Research Basic Course* and select either Biomedical or Social-Behavioral-Educational, depending on the focus of the research protocol.
    c. Complete the training, ensure 80% score on each module quiz.
    d. Completion and scores are stored by CITI and sent to HRPP.
    e. Print or save scores and completion certificate, **recommended**.
3. **For investigators and study personnel with an existing CITI account**
    a. Log in using your CITI log in credentials and scroll down to open the "Affiliate With Another Institution" section; select Virginia Polytechnic Institute & State University.
    b. Navigate to "Previously Completed Coursework" and ensure completion of the *Human Subjects Research Basic Course* with 80% score for each module quiz within the past 3 years.
    c. If 3 years have passed since completion of the *Human Subjects Research Basic Course*, navigate to and complete the appropriate Refresher Course (Biomedical or Social-Behavioral-Educational) with 80% score for each module quiz.

Signed/Dated:

HRPP Director

Associate Vice President for Scholarly Integrity and Research Compliance

Effective: January 21, 2019

Date last reviewed (every 3 years):