Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-023.0
Policy Title: Educational Requirements

Purpose:

The purpose of this policy is to set forth educational requirements to be met by research personnel, members of the Institutional Review Board, and HSPP staff.

Definitions:

See policy 2011-007.0 for definitions of:

Human Subject	Research

Policy:

It is the policy of the HSPP that individuals directly involved in the conduct of humans subject research (i.e. investigators, coordinators, persons obtaining consent) or administration of human subjects research (i.e. HSPP staff, IRB members) complete training in the protection of human subjects in research.

The training requirement is most often satisfied initially through completion of an on-line training tutorial provided through the Collaborative IRB Training Initiative (CITI). Alternate mechanisms of training may be accepted by the Director (or designee) of the HSPP or by IRB staff on a case-by-case basis if that mechanism is also an established training tool (e.g., an NIH sponsored tutorial). The HSPP/IRB may review the content of alternate mechanisms to determine if it is an acceptable alternative. The IRB reserves the right to require an individual to complete any/all modules of the CITI program.

Training of study personnel is required regardless of whether the research qualifies for exempt, expedited or full board review, or whether the facilitated review process is utilized. For all research, training of study personnel must be current at the time of initial approval. Training must also be current for an individual added to a study through a request for modification. For exempt research, the PI is responsible for ensuring that training is current for personnel added to the study after initial approval.

Training will be considered current if completed within the past three years. The CITI course, NIH training tutorial, attendance at the annual IRB combined panel meeting, or other appropriate mechanism as noted above, will fulfill the renewal requirement.

All newly appointed IRB members are required to complete CITI training before being assigned as a primary reviewer.

If an investigator is external to the UConn Health, they must submit proof of having completed human subjects protection training. The IRB reserves the right to require the external investigator to provide a letter from their home institution's IRB certifying compliance with local training requirements, and/or to require the investigator to complete some or all of the elements of the CITI training modules.

Additionally, the HSPP strongly encourages individuals acting as the Principal Investigator for the first time at UConn Health to partake in an educational session with the Educational Specialist (ES), or a Research Compliance Monitor (RCM), prior to initiation of their first study at UConn Health. The IRB may also mandate this as a condition of approval.

The ES within the HSPP will also offer voluntary educational opportunities to research personnel and to HSPP staff and IRB members. The ES will be primarily responsible for developing and implementing these opportunities which may include, but are not limited to, brown-bag lunch sessions, publication of a departmental newsletter, tailored educational sessions as requested, hosting professional conferences,

conducting education at an IRB meeting, convening combined IRB panel meetings to review policies and current developments, HSPP staff attendance at conferences etc.

The ES will communicate changes to HSPP policies and/or forms, and general educational information, to the research community. Acceptable means of communication include broadcast notices, emails, and newsletters.

Procedure:

CITI:

Individuals log into the CITI web site to complete the applicable training module based on their primary research function. Individuals self-select from training courses established within the CITI program (e.g., IRB Members /HSPP staff; biomedical investigators, social and behavioral investigators, students).

Upon receipt of the completion report from CITI, designated IRB staff enter the course completion information into the IRIS database if a user account exists and onto an excel spreadsheet.

- Most often notification will come directly from CITI to designated IRB staff, however if another mechanism was used to satisfy the training requirement, or CITI completion was affiliated with another institution, the evidence of training may be incorporated into the IRB submission material. In such cases the material within the submission will be utilized to update the training information.

Designated IRB staff verify that all investigators and research staff have completed required training by checking the names on an IRB submission, against the database and/or spreadsheet information if necessary. Verification is study specific and done at the time of initial review, or for an individual being added via a request for modification.

- If an individual on the application has not completed the training the IRB staff will notify the PI and the individual through the IRIS system via a contingency for approval.
- The PI may choose to remove the individual from the study and add him/her back via a modification at a later date or to wait until the individual completes the training.
    - If the individual is to remain on the study, final IRB approval will not be released until the requirement is satisfied.
        - If subjects are on active treatment, the PI must request in writing permission from the IRB Chair to continue the research for those subjects already enrolled, confirming that training is in the process of being completed.

The IRB Regulatory Specialists will remind IRB members of their renewal requirements in order to serve as a primary reviewer. Sign-in sheets will be utilized to track attendance at the IRB combined panel meeting.

Use of Alternative Training Mechanism:

Alternative mechanisms must be established mechanisms (e.g., NIH training tutorials). If not established and known to the IRB, the individual must provide the DHSPP with an overview of the content of the proposed substitution and an explanation for why the alternative mechanism is being sought. The DHSPP will issue a written determination as to whether the exception is granted. The PI will include evidence of this exception as part of the IRB submission process.

First Time PI:

Information is solicited during the IRB application process as to whether the individual is a first time PI. If checked yes, the IRB approval letter directs the individual to meet with the ES/RCM. The ES/RCM also receives a copy of this letter and pro-actively reaches out to schedule such sessions.

Obtaining / Sharing Information:
The HSPP administrator ensures mechanisms are in place for continuing education, e.g., through subscriptions to CITI, and to list serves. The HSPP Administrator, or designee, or ES, will share educational information with researchers and IRB staff and member. Mechanisms used to share information will include broadcast messages, email communications, postings to the HSPP / IRB web site. Messages may be in regard to changes in policies, regulations or to recent developments, internal or external to the Health Center. If applicable, effective dates for implementation will be included in the message.

Related Content

2009-005.0 – Monitoring of IRB Approved Studies

Basis

Terms of Federal Wide Assurance
45 CFR 46.107

Document Attributes:

Date Effective: 6/5/2023

Replaced Version: 2/5/2018

Reviewed and Approved By:

Richard H. Simon	*6/5/2023*
Richard H. Simon, MD **Director Human Subjects Protection Program**	**Date**