**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:

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|---|---|
| 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. Training of study personnel is required regardless of whether the research qualifies for exempt, expedited or full board review.

The training requirement is most often satisfied through completion of an on-line training tutorial approved by the Director of the HSPP. While on-line modules provided through the Collaborative IRB Training Initiative (CITI) are currently used to satisfy the general training requirement, the DHSPP may change the mechanism of required training. The IRB also reserves the right to require an individual to complete any/all modules of the CITI program, beyond the modules contained in the CITI course that is self-selected (see procedures section).

For UConn Health employees, students and IRB members, training must be renewed every three years. The CITI course, attendance at the annual IRB combined panel meeting, or other mechanism approved by the DHSPP, will fulfill the renewal requirement.

All newly appointed IRB members are required to complete the CITI IRB course before being assigned as a primary reviewer. A members training must continue to be current in order to serve as a primary reviewer.

If an individual would like to satisfy the human subject training requirement through some other means, that person must obtain approval from the Director of the HSPP (DHSPP). The individual must provide the DHSPP with an overview of the content of the proposed substitution.

If an investigator is external to the UConn Health, s/he must submit proof of having completed human subjects protection training. A letter or certificate of completion from the respective institution or the NIH certificate may suffice. However, the IRB reserves the right to require the external investigator to provide a letter from his/her 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 training module used to satisfy the UConn Health IRB requirement.

Additionally, the HSPP requires that individuals acting as the Principal Investigator for the first time at UCHC partake in an educational session with the Educational Specialist (ES), or a Research Compliance Monitor (RCM), prior to initiation of his/her first study at UConn Health.

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 one of four training courses established within the CITI program (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 database and onto an excel spreadsheet.

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 information. Verification is study specific and done at the time of initial review, continuing review and/or requests for modification to add study personnel.

- 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.
- 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. A directive from the PI will suffice for the IRB staff to process the submission accordingly and for the review to move forward.
    - 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 IRIS system generates reminder notices to request continuing approval. Such notices will remind the PI to ensure that all study personnel are up to date with their training.

The IRB Regulatory Specialists will remind IRB members of their renewal requirements in order to serve as a primary reviewer. The HSPP Administrator or designee will maintain a list of training status for all HSPP staff, IRB support staff and IRB members to verify compliance with policy.

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 HSPO 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:***

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**Reviewed and Approved By:**

*Richard H. Simon* *17 August 2017*

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**Director Human Subjects Protection Program**