

## Section 4: Education and Training

### Policy

UIR policy requires all individuals who are involved either in the performance of research or the oversight of research to be trained in human research protection issues. The type and amount of training required is contingent upon the individual's role in the performance and oversight of the research.

### Procedures

#### 4.1. IRB Members

The Research Support Services Specialist will provide new IRB members with an orientation of the history of human subjects' protections, ethical principles, pertinent federal regulations, and specific institutional policies and procedures. Each member is provided a copy of the Belmont Report, 45 CFR 46, Food and Drug Administration regulations, institutional policies and procedures, a list of resources that includes pertinent web sites, and any other material that is deemed necessary at that time. Along with this orientation the new member will also:

- Complete [CITI training](#) course Behavioral and Social Science training modules OR Biomedical and Biological Sciences training modules AND [UIC HSP 105 HIPAA training](#). Instructions can be found at [IRB Required Online Training](#).
- The Research Support Services Specialist will give an orientation as how to register and use IRBNet.
- New members will be assigned a mentor who is an experienced IRB member who will guide the new member in his/her review of 3-4 protocols (or until the new member feels comfortable), UIR policies and procedures, federal, and state regulations.

#### Continuing Education

- Every two years IRB members must become re-certified in human subjects' protection by completing CITI training (individually or during an IRB meeting) or other continuing education training by organizations such as PRIM&R.
- Research Support Specialist will distribute a variety of publications to IRB members.
- A portion of each meeting is dedicated to the discussion of new and relevant training information.

#### 4.2. Research Support Services Staff

Research Support Services (RSS) staff will be expected to maintain familiarity with 45 CFR 46 Protection of Human Subjects (OHRP), 21 CFR 50 Protection of Human Subjects(FDA), 21 CFR 56 Institutional Review Boards (FDA), UIR Policy & Procedures manual, and stay abreast of any changes in requirements by OHRP and the FDA. Research Support Services staff will also complete [CITI training](#) , [UIC HSPP 105 HIPAA training](#), and attend a continuing education course annually such as the Public Responsibility in Medicine and Research (PRIMR) meetings or other training.

### **4.3. Investigators and Research Staff**

#### **Policy**

UIR policy requires all individuals who are involved in the performance of research to be trained in human subject research protection issues prior to their involvement in human subject research. The type and amount of training required is contingent upon the individual's role in the performance of the research. UIR requires evidence of continuing education every two years.

#### **Procedures**

UIR requires all individuals who conduct human subject research to be appropriately trained prior to conducting human subject research. In addition, continuing education is required every two years. Investigators are asked to list all individuals who will work on the research protocol.

RSS will review and determine whether appropriate initial and continuing training has taken place for each person listed on the protocol. If an investigator or research staff has not completed initial or continuing education training, the protocol/continuing review will not be approved. If an individual listed on the protocol has not completed training, he or she will be informed of this as part of the RSS review. The staff member must complete the training in order to remain on the protocol, or his or her name will be removed from the protocol at the time of protocol approval. If a name is removed, it may be added in the form of an amendment at a later date, after training is completed.

- All training activities are maintained in Research Support Services. A spreadsheet of individuals who have completed CITI and HSPP 105 HIPAA training will be maintained.

Any individual listed as a principal investigator (PI) on a research protocol that involves any intervention or interaction with research subjects, must complete the CITI training regardless of whether or not they have completed training programs at other institutions. This is a requirement regardless of whether or not the PI actually performs the research procedures. A PI has ultimate responsibility for compliance with human subject protections and, therefore, must complete this training. There are two different module tracks, Biomedical and Behavioral and Social Science, and researchers will complete the appropriate module.

Any other individual (e.g., co-investigator, key personnel) listed on the protocol that does or does not intervene or interact (including obtaining informed consent) with a research subject is required to complete the web-based CITI training program.

## **Lapse in Training**

If a lapse in training happens during an active protocol the following will take place:

1. If the individual with the expired training is the PI, he or she will need to renew the training at the time of a continuing review or amendment. If this is not promptly addressed the IRB may request the identification of a new PI, or the protocol will be administratively closed.
2. If the individual with the expired training is key research personnel, he or she will need to renew their training at the time of a continuing review or amendment. If this is not promptly addressed the individual(s) will be removed from the protocol.

## **New Principal Investigator Orientation**

Any new principal investigator for a protocol that intervenes or interacts with research subjects is required to meet with RSS staff to receive a brief PI orientation. A PI is defined as new if this is their first protocol application, or they are new to the institution and are submitting their first application. The purpose of this orientation is to provide an overview of PI responsibilities and to train them in how to use IRBNet and go over regulatory issues. A PI's protocol will not be submitted for review until this orientation has been completed.

## **Continuing Education**

All investigators and associated research staff that are listed on a human subject protocol application will be required to complete continuing education every two years. This includes principal investigators, co-investigators, research staff, and all other key personnel. Continuing education may be accomplished by completing a CITI refresher course.