

IRB PROCEDURE STATEMENT

Procedure: Training Requirements

Procedure ID: 15-12-001

Effective: December 2, 2015

Revised: January 17, 2019

A. Background

To ensure that all personnel involved in the conduct or review of human subjects research receive appropriate education on the ethical principles and regulatory requirements related to human subjects protection, all key personnel,* IRB members and IRB staff must complete the human subject research training once every five years.

Training is offered via the web-based Collaborative Institutional Training Initiative (CITI) site. The Office of Research Compliance periodically provides in-person training that will meet the requirement for key personnel. Training information and instructions can be found on the BGSU IRB webpage.

*Key personnel are defined as research personnel who are directly involved in conducting research with human subjects through an interaction or intervention for research purposes, OR who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting a research study. Examples include:

- Principal Investigators
- Advisors of student Principal Investigators
- Obtaining consent or screening potential subjects
- Conducting study procedures
- Analyzing research data that contain personally identifying information

B. Procedure

1. Basic Training

The Basic Human Research Course is required for people who have not previously completed a CITI human subject research course or the full in-person human subjects training course offered by the BGSU Office of Research Compliance.

Training Requirements

If a person completed basic CITI training at another institution, the person needs to confirm that the course modules that were previously taken match the modules required by BGSU. If BGSU accepts the CITI training completed while at another institution, the five-year expiration date will be based upon the course completion date.

- Key Personnel
 - There are two basic educational tracks for researchers: Biomedical Research or Social and Behavioral Research. A person should choose the track most closely related to the research in which s/he is involved.
 - If a person has not previously completed the Basic Human Research Course, taking a refresher course will not satisfy the training requirement.

- IRB Members
 - There is one educational track for IRB members: IRB Members.
 - The IRB Member course is similar to the basic training for researchers but contains additional information. Since this basic training is required for all new IRB members, it will also serve as an acceptable substitute for the basic training required for key personnel.
 - If a person has not previously completed the Basic IRB Member Course, taking a refresher course will not satisfy the training requirement.

- IRB Staff
 - All new IRB staff will complete either the Basic Human Research Course or the IRB Member Course, depending upon which course is most relevant for the individual.
 - If a person has not previously completed the Basic Human Research Course or the IRB Member Course, taking a refresher course will not satisfy the training requirement.

2. Refresher training

Individuals must complete the Refresher Human Research Course when it is time to renew their human subjects training. The refresher training is an abbreviated version of the basic training. Refresher training will be valid for five years after the training completion date. If an individual completes basic training again, this will meet the requirement for refresher training.

Any time an acceptable and appropriate training is completed a new training expiration date will be given, which is five years after the training completion date (e.g., a new IRB member complete basic IRB member training, a professor participates in a full in-person training session, etc.).

If a person completed refresher CITI training at another institution, the person must confirm that the course modules that were previously taken match the modules required by BGSU. If BGSU accepts the CITI refresher training completed while at another institution, the five-year expiration will be based upon the course completion date.

- Key Personnel
 - There are two refresher educational tracks for researchers: Biomedical Research or Social and Behavioral Research. A person should choose the track most closely related to the research in which s/he is involved.

Training Requirements

- IRB Members
 - There is one educational track for IRB members: IRB Members.
 - The IRB Member refresher course is similar to the refresher training for researchers but contains additional information. Since this training is required for IRB Members, it will also serve as an acceptable substitute for the refresher training required for key personnel.
- IRB Staff
 - IRB staff will complete either the refresher training required for key personnel or the IRB Member training, depending upon which course is most relevant for the individual.

3. Training Verification

The Office of Research Compliance will verify that the training requirements for key personnel have been satisfied at the time of new protocol submission and/or at the time of continuing review. Submissions will not be reviewed unless all key personnel have satisfied the training requirement.

IRB member training is verified by the ORC within two months of new appointments and yearly for existing IRB members.

The IRB Chair verifies IRB staff training on an annual basis.

4. Implementation

Training requirements and the verification processes are effective as of the date of this procedure statement, with the exception of refresher training verifications to occur on and after February 1, 2019.