IRB PROCEDURE STATEMENT

Procedure: Human Subjects Research Training Requirements

Procedure ID: 2022-01   **Effective:** December 2, 2015
                                   Revised: February 1, 2019; May 2022

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.

Examples include:
- Principal Investigators (PI)
- Advisors of students who are Principal Investigators
- Research assistants who are:
  - obtaining consent or screening potential subjects
  - conducting study procedures
  - analyzing research data that contain personally identifying information

***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.

Training is offered via the web-based *Collaborative Institutional Training Initiative Program* (CITI) site (https://about.citiprogram.org/). Training information and instructions can be found on the BGSU IRB webpage at IRB Training Information. The appropriate CITI Human Subjects Research courses are required for people who are working with human subjects and are categorized Basic Courses, Refresher Courses or IRB Member Courses. Within these courses the focus of Biomedical (Biomed) or Social-Behavioral-Educational (SBE) Focus is chosen for the course.

B. Procedure

1. Initial IRB Training

The Basic Courses are required for people who have not previously completed a *Collaborative Institutional Training Initiative Program* (CITI) human subjects research

course or any other human subjects training course.

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 5-year expiration date will be based upon that course completion date.

- Key Personnel
  - There are two basic educational tracks within the Basic Courses for researchers: Social-Behavioral-Educational (SBE) Research or Biomedical (Biomed) 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 a Basic Research Course, taking a Refresher Course will not satisfy the training requirement.

- IRB Members
  - IRB members should take one IRB Member training course (i.e., IRB Member – Biomedical Focus, IRB Member – Social Behavioral-Education Focus, or IRB Member – Biomedical and Social-Behavioral Educational Combined).
  - The IRB Member course is similar to the basic training for researchers but contains additional information.
  - If a person has not previously completed an IRB Member Course, taking a refresher course will not satisfy the training requirement.

- IRB Staff
  - All new IRB staff should complete either the Basic Research Course for Biomedical research investigators or Social-Behavioral-Educational research investigators. In addition, the staff may also choose to complete the course for IRB Members, depending upon which course is most relevant for the individual.
  - If a person has not previously completed the Basic Research Course or the IRB Member Course, then taking a Refresher Course will not satisfy the training requirement.

2. Refresher Training

Individuals must complete a Refresher Research Course when it is time to renew their human subjects training. The Refresher Course (training) is an abbreviated version of the Basic Course (i.e., initial human subject research training). Refresher training will be valid for 5 years after the training completion date. If an individual completes one of the Basic Courses 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 5 years after the training completion date (e.g., when a new IRB member completes an IRB Members training course.

If a person completed a Refresher Course of 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 Course completed while at another

institution, the 5-year expiration will be based upon the course completion date.

- Key Personnel
  - There are two focus areas under the Refresher Courses: Biomedical or Social-Behavioral-Educational Research. A person should choose the track most closely related to the research in which s/he is involved.

- IRB Members
  - There is one IRB Members - Basic/Refresher Course for the IRB Committee members.
  - The IRB Member Basic/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 if the IRB member is a part of a research project.

- IRB Staff
  - IRB staff will complete either the refresher training required for key personnel or the IRB Member refresher training, depending upon which course is most relevant for the individual.

3. Training Verification

The Institutional Review Board Staff 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 IRB 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.