



TITLE: TRAINING AND EDUCATION	SOP NO.: IRB 102
EFFECTIVE DATE: 2/24/2025	REVISION NO.: 01

1. PURPOSE

- 1.1. Training of Institutional Review Board (IRB) staff and IRB members is critical to fulfilling its mandate to protect the rights and welfare of research subjects consistently throughout the UMBC research community. The training and education of those who conduct research is equally important to ensure that human subjects are being adequately protected. Therefore, training and continuing education is valued and required for IRB staff, IRB members, and for those conducting human subject research at UMBC.
- 1.2. SCOPE: This SOP applies to UMBC IRB staff and IRB members. The SOP also applies to those who conduct human subject research at UMBC and its affiliates, namely investigators and key study personnel.

2. DEFINITIONS

- 2.1. IRB – Institutional Review Board
- 2.2. SOP – Standard Operating Procedure
- 2.3. Key study personnel - are individuals engaged in the conduct of research activity, including investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the research.



3. POLICIES

The IRB Manager or designee, in consultation with the IRB Chair, establishes the educational and training requirements for IRB staff and IRB members. IRB staff and IRB members receive initial training and continuing education regarding the responsible review and oversight of human subject research including the UMBC IRB standard operating procedures (SOPs).

IRB members must complete initial training and continuing education on human subject research ethics and regulations. As appropriate, instruction pertaining to existing or new IRB SOPs is provided to IRB members. Investigators and key study personnel conducting research at UMBC and its affiliates must complete the Collaborative IRB Training Initiative (CITI) human subject research training program. The individual must complete CITI's Human Subjects Social/Behavioral Research Course; the IRB Office reserves the right to require research personnel to complete additional training courses applicable to their field of research (e.g., biomedical).

All investigators and key study personnel conducting human subjects research must complete CITI training regardless of funding sources or federal oversight. CITI training must be recertified every five years. Investigators and key study personnel conducting research must complete training before the research can be activated at UMBC.

4. PROCEDURE

4.1. IRB Staff Training

- 4.1.1. IRB staff must complete human subject research CITI training. The required CITI training for IRB staff is titled 'IRB Member.' Verification of training is recorded in the UMBC online IRB management system Quali, provided that users login with the organizational "Single Sign On" process.
- 4.1.2. IRB staff must complete initial training and continuing education. A training and education plan approved by the IRB Manager, in consultation with the IRB Chair, is provided to IRB staff. Training and



continuing education requirements are outlined in the plan. IRB staff members should retain documentation of the completion of any required training.

- 4.1.3. IRB staff are encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research. The UMBC IRB supports such activities to the extent possible and as appropriate for staff responsibilities. Attendance may be used toward continuing education requirements as determined by the IRB Director or designee, in consultation with the IRB Chair. Certificates of completion should be retained by the IRB staff member.
- 4.2. IRB Member Training
 - 4.2.1. IRB members must complete human subject research CITI training. The required CITI training for IRB members is titled 'IRB Member.' Verification of training is recorded in the UMBC online IRB management system Quali, provided that users login with the organizational "Single Sign On" process.
 - 4.2.2. IRB members must complete initial training and continuing education in areas germane to their responsibilities. The options for training and continuing education must be approved by the IRB Manager or designee, along with the IRB Chair. The method of documenting completion of training or continuing education is determined by an IRB Manager or designee.
 - 4.2.3. IRB members are encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research. The UMBC IRB supports such activities to the extent possible and as appropriate for member responsibilities. Certificates of completion should be retained by the IRB member and may be submitted to the IRB office as necessary.
 - 4.2.4. IRB Chair(s) and IRB Vice-Chair(s) receive supplementary training in areas germane to their additional responsibilities as necessary.
- 4.3. Investigator and Study Personnel Training
 - 4.3.1. Investigators and key study personnel must provide a certification of completion or recertification of the CITI Human Subjects Social/Behavioral Research Course. The completion certificate must



be routed to the UMBC IRB to conduct human subject research. Verification of training is recorded in the UMBC online IRB management system Kualu, provided that users login with the organizational “Single Sign On” process.

- 4.3.2. A specific circumstance that research personnel may opt for CITI's No More than Minimal Risk training course, is when those research personnel are students in a UMBC course, their course instructor is the PI of the IRB protocol, that PI has completed the Human Subjects Social/Behavioral Research Course, and the students' research projects are covered by the PI's protocol. In such a case, each student may be added as research personal and approved on the basis of completing CITI's No More than Minimal Risk training course.
- 4.3.3. Investigators and key study personnel must provide a certificate of completion for other required training (e.g., SIRB training) to UMBC. Verification of training is recorded in Kualu.
- 4.3.4. Investigators and key study personnel may complete required training concurrently during the initial IRB review process of the research. The IRB staff verifies the completion of required training program(s) by investigators and key study personnel before notification of final approval, or required revisions, is issued and the application is moved to the next respective status in Kualu.