



SOP 102: TRAINING AND EDUCATION

PURPOSE

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 University of Utah 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 the University of Utah.

SCOPE

This SOP applies University of Utah IRB staff and IRB members. The SOP also applies to those who conduct human subject research at the University of Utah and its affiliates, namely investigators and key study personnel.

DEFINITIONS

- A. Affiliated institutions** (i.e., affiliates) have a Memorandum of Understanding (MOU) with the University of Utah designating the University of Utah IRB as the IRB of record. The University of Utah IRB has oversight of research conducted at affiliated institutions.
- B. 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.

POLICY

The IRB Director or designee 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 University of Utah 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 the University of Utah and its affiliates must complete the Collaborative IRB Training Initiative (CITI) human subject research training program. The individual must complete the modules pertinent and applicable to their field of research (that is, biomedical or social/behavioral sciences). All investigators and key study personnel conducting a clinical trial must also complete Good Clinical Practice (GCP) training regardless of funding sources or federal oversight. CITI and GCP training must be recertified every three years. Investigators and key study

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personnel conducting research under the Single IRB (SIRB) model must complete SIRB training before the research can be activated at the University of Utah.

PROCEDURES

1. IRB Staff Training

- 1.1. IRB staff must complete human subject research training. IRB staff may complete the training offered for researchers that is approved by the University of Utah IRB. Verification of training is recorded in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA).
- 1.2. IRB staff must complete initial training and continuing education. A training and education plan approved by the IRB Director 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.
- 1.3. IRB staff are encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research. The University of Utah 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. Certificates of completion should be retained by the IRB staff member.

2. IRB Member Training

- 2.1. IRB members must complete human subject research training. IRB members may complete the training offered for researchers that is approved by the University of Utah IRB. Verification of training is recorded in ERICA.
- 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 Director or designee. The method of documenting completion of training or continuing education is determined by an IRB Manager or designee.
- 2.3. IRB members are encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research. The University of Utah 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.
- 2.4. IRB Chair(s) and IRB Vice-Chair(s) receive supplementary training in areas germane to their additional responsibilities as necessary.

3. Investigator and Study Personnel Training

- 3.1. Investigators and key study personnel must provide a certification of completion or recertification to the University of Utah IRB to conduct human subject research. Verification of training is recorded in ERICA.

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- 3.2. Investigators and key study personnel must provide a certificate of completion for other required training (e.g., GCP training, SIRB training) to the University of Utah. Verification of training is recorded in ERICA.
- 3.3. Investigators and key study personnel may complete required training concurrently during the initial IRB review process of the research. The IRB coordinator verifies the completion of required training program(s) by investigators and key study personnel before notification of final approval is issued and the application is moved to an approved status in ERICA.
- 3.4. The Office of the Vice President for Research offers continuing education and training opportunities through the Office of Research Education (REd) designed to support, develop, and maintain a standardized body of knowledge and best practice methodology for all research personnel at the University of Utah. Investigators and key study personnel have an open invitation to attend or complete as many of the educational sessions as available. Certificates of completion should be retained by the individual completing the training or continuing education.

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