



## **SOP 104: IRB AUTHORITY AND SIGNATORY AUTHORITY**

### **PURPOSE**

This SOP outlines the specific authority granted to the University of Utah Institutional Review Board (IRB) to review, approve, and monitor research involving human subjects as a component of the Human Research Protection Program at the University of Utah.

### **SCOPE**

This SOP applies to the University of Utah IRB and those with signatory authority for the IRB.

### **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. The Federalwide Assurance (FWA)** is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research.
- C. The Institutional Official** is ultimately responsible for the oversight and conduct of the Human Research Protection Program of which the IRB is a component.

### **POLICY**

The Vice President for Research has been designated by the Board of Trustees and the University of Utah President to serve as the Institutional Official on the University of Utah's Federalwide Assurance with the Office of Human Research Protection (OHRP) which also serves as the Food and Drug Administration (FDA) registration for IRBs.

The University of Utah Administration through the Vice President for Research grants the University of Utah IRB authority to approve research activity, specify modifications required to secure IRB approval of the research activity, or disapprove any research activity overseen and conducted by the University of Utah and its affiliates. The University of Utah IRB may suspend or terminate approval of research that is not being conducted in accordance with the IRB's policies, is not in compliance with federal regulations, or that is associated with unexpected, serious harm to participants. The University of Utah IRB also has the authority to observe or have a third party observe the consent process, and the conduct of the research.

Research that has been approved by the University of Utah IRB may be subject to further review and approval or disapproval by officials of the University of Utah, as appropriate. However, University of Utah officials may not approve the research if it has not been approved by the University of Utah IRB.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



The IRB Director, IRB Chair(s), and IRB Vice Chair(s) are authorized to sign any documents in connection with the review and approval of research projects involving the humans subjects, which have been reviewed and approved pursuant to University of Utah IRB policies and procedures. The IRB Chair may designate signatory authority to qualified IRB members and IRB staff members, as appropriate. In all cases, individuals must sign their own name and indicate their title under their signature.

Electronic signatures via the Electronic Research Integrity and Compliance Administration system (ERICA) are considered valid. Individuals must electronically approve items using their secure login. ERICA is password protected and limited to only those individuals directly connected with the project and the appropriate regulatory staff. ERICA records the individual by name and their electronic approval (i.e., electronic signature), and all actions taken by that individual. The results of IRB review, actions, and decisions are issued through ERICA and is further described in IRB SOP 305: Documentation.

Any action, letters, memos, or emails between the IRB, and/or members of the faculty or staff of the University of Utah that provides information concerning the review of research protocols by the IRB or IRB staff which do not imply or appear to imply approval of the research protocol, may be signed by designated IRB staff members.

Any letters or memos sent to agencies of the federal government, funding agencies (whether private or public) or their agents on behalf of the University of Utah IRB are signed by the Institutional Official, IRB Director, IRB Chair or designee. Letters or memos may be signed with an electronic signature.

Any letters, memos or email sent representing the decision or opinions of the IRB Chair or designee, may be signed by the IRB Chair or designee, as long as such correspondence does not imply review and approval of research projects.

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