SOP 101: POLICIES AND PROCEDURES MANAGEMENT

PURPOSE

University of Utah Institutional Review Board (IRB) standard operating procedures (SOPs) provide a framework for the ethical and scientifically sound conduct of human research. This SOP outlines the University of Utah IRB practice for creating, publishing, and routine review of its policies, procedures, and guidance documents. Supported by institutional policies and written procedures, the IRB SOPs ensure that the rights and welfare of human research subjects are overseen and protected uniformly, regardless of personnel changes.

SCOPE

This SOP applies to the University of Utah Institutional Review Board and staff.

POLICY

The University of Utah Institutional Review Board functions independently. Federal regulations governing human subjects research, and the University of Utah Administration, through the Vice President for Research, grant the IRB this authority as part of the Human Research Protection Program.

The IRB maintains an active Federal Wide Assurance (FWA) and agrees to apply 45 CFR 46 whenever the University of Utah is engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) of the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

Research that is not federally funded, supported or otherwise subject to federal oversight, and that is outside of the FWA is subject to commensurate protections by the University of Utah IRB except where otherwise described in University of Utah IRB policy (see IRB SOP 105: Non-Federally Funded Research).

The IRB adheres to 21 CFR 50 and 56 for clinical investigations regulated by the Food and Drug Administration (FDA). The IRB applies the principles of the International Conference on Harmonization's Good Clinical Practices (ICH-GCP) to clinical investigations, as adopted by the FDA and insofar as the standards and requirements are consistent with 21 CFR.

The University of Utah IRB applies the standards of the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) to research that involves the use of protected health information.

PROCEDURES

1. **Review, Approval, and Revision of IRB SOPs**

   1.1. If the creation of a new SOP is necessary, the SOP will be sent to the full IRB Executive Committee for review and approval.

1.2. Each SOP that has been approved and published on the IRB website will be reviewed no less than three years from the date of approval as described in this policy. The review date is determined as three years from the last date of approval. The IRB Director may extend the review date as deemed necessary.

1.3. For the review of an approved SOP, an IRB Administrator initially reviews the SOP for consistency with state or federal guidelines, current practices or institutional polices. If minor clarifications and changes are necessary, the IRB Administrator provides the revised SOP to a designated member(s) of the IRB Executive Committee for approval. If the IRB Administrator determines that significant changes to a policy must be made, the revised SOP may be sent to the full IRB Executive Committee for approval.

1.4. Review and approval of the SOP is documented by an IRB Administrator who records the date approved, and the IRB Executive Committee member(s) responsible for approval. The approval date is the effective date.

2. SOP Dissemination

2.1. Any new or revised SOP is disseminated to IRB members and IRB staff by an IRB Administrator. Record of dissemination and any applicable training is documented by the IRB Administrator.

2.2. Approved SOPs are posted on the IRB website by an IRB Administrator or designee.

3. Creating and Using IRB Forms

Forms are used to ensure that policies are integrated into the daily research and review operations and enable the IRB to manage review, tracking, and notification functions consistently. Forms are not subject to the same standards of control cited in sections 1 and 2. Forms include checklists, applications, and automated notifications sent by the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA).

3.1. Forms are created and revised by IRB administrators or designee under the direction of the IRB Director.

3.2. As applicable, forms are implemented in the ERICA online system by the ERICA programmer(s).