SOP 101: POLICIES AND PROCEDURES MAINTENANCE

POLICY
The University of Utah Institutional Review Board (IRB) 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 Plan. The IRB maintains a current Federal Wide Assurance (FWA) and follows the regulations and guidance of the Office for Human Research Protections (OHRP) for all studies conducted under that assurance. Research that is not federally funded and that is outside of the FWA is subject to the same scrutiny except where otherwise described in University of Utah IRB policy (see SOP 105: Non-Federally Funded Research). The IRB follows the regulations and guidance of the U.S. Food and Drug Administration (FDA), and the International Conference on Harmonization (ICH), as applicable.

Standard Operating Policies and Procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research. Supported by institutional policies and written procedures, the IRB ensures that the rights and welfare of human research subjects are overseen and protected uniformly, regardless of personnel changes.

PROCEDURES

1. Procedures for Review, Revision and Approval of Policies and Procedures

Changes to regulations, federal guidelines, research practices, or University of Utah policies and procedures may require a new SOP or revision of a previously issued SOP.

Each approved SOP 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.

1.1. The IRB Director or designee reviews the SOP and provides the revised policy and procedure to a designated member(s) of the IRB Executive Committee for approval. If the IRB Director or designee determines that significant changes to a policy must be made, the revised policy and procedure may be sent to the full Executive Committee for approval.

1.2. The review and approval of the SOP is documented by an IRB Administrator or designee who records the policy and procedure, the date approved (e.g. mm/dd/yyyy) and the member(s) responsible for approval. The approval date is the effective date.

2. Procedures for SOP Dissemination and Training

When new or revised SOPs are approved, they will be disseminated to the appropriate individuals and departments.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.
2.1. Any new or revised policy or procedure or new regulation is disseminated to the IRB members and staff by the IRB administrator or designee. Record of dissemination and any applicable training is documented by the IRB administrator or designee.

2.2. New IRB members or staff must review all applicable SOPs and regulations as well as complete currently required human subjects training prior to undertaking any IRB responsibilities. Evidence of human subjects training must be documented and filed with the IRB Executive Secretary or designee.

3. Procedures for 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 standards of control cited in sections 1 and 2. Forms include checklists, applications, and notifications.

3.1. Forms are created and revised by IRB Administrators or designee.

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