

Approved by IRB Executive Committee: February 2, 2007  
Supersedes Document Dated: November 15, 2005; November 9, 2005  
AAHRPP Elements I.1.D. and I.3.A.

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**POLICY**

The University of Utah Institutional Review Board (IRB) functions independently. 45 CFR 46 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), the U.S. Food and Drug Administration (FDA), and the International Conference on Harmonization (ICH).

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.

- 1.1. The IRB Director or designee provides the revised policy and procedure to the IRB Executive Committee consisting of the IRB Chair, IRB Vice-Chairs and other designated IRB members for approval.
- 1.2. The review and approval of the IRB Executive Committee is documented by the IRB Director or designee who records the policy and procedure, the date approved (e.g. mm/dd/yyyy) and the members voting in favor of approval. In order for revised policy to be approved, a simple majority of the IRB Executive Committee must vote in favor of the revision. In all cases the IRB Executive Committee will strive to reach unanimous consensus for revised policies and procedures.

The approval date (or effective date) appears on the approved policy and procedure. 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.

**2. Procedures for SOP Dissemination and Training**

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

- 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 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 templates, checklists, (electronic) application forms 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).