

Approved by IRB executive committee: August 13, 2008
Supersedes Document Dated: February 6, 2008, November 15, 2005; November 9, 2005
AAHRPP Element: I.3.B.

POLICY

The University of Utah Administration through the Vice President for Research grants the IRB authority to approve research activity, specify modifications required to secure IRB approval of the research activity, disapprove all research activity overseen and conducted by the University of Utah. The IRB may suspend or terminate approval of research not being conducted in accordance with the IRB's policies, is not in compliance with Federal Regulations or that had been associated with unexpected serious harm to participants. The 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 an IRB may be subject to further review and approval or disapproval by officials of the University of Utah, as appropriate. However, University officials may not approve the research if it has not been approved by the IRB.

The IRB Director, IRB Chair(s), and IRB Vice Chair(s) are authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as subjects, which have been reviewed and approved pursuant to University of Utah policies and procedures. This policy applies to the IRB Director and all staff of the IRB. In all cases individuals must sign their own name and no other and indicate their title under their signature.

The Electronic Research and Compliance Administration (ERICA) is password protected and limited to only those individuals directly connected with the project and the appropriate regulatory staff. The ERICA system records the individual by name and their electronic approval (i.e. electronic signature), and all actions taken by that individual.

Authorization to sign documents not described in this policy may be made in writing by the Associate Vice President for Research Integrity.

PROCEDURES

1. Results of Reviews, Actions and Decisions

- 1.1. The results of reviews and actions taken by the convened IRB that grant or may appear to grant Investigators with initial or continuing approval of research, training or educational projects involving human subjects, must signed off by the IRB Director, the IRB Chair, IRB Vice Chair or IRB member designated by the IRB Chair (i.e. designated expedited reviewer), except when the convened IRB approves research as submitted. All results and actions taken by the IRB will be reflected and recorded in ERICA.

- 1.1.1. If the convened IRB approves research as submitted, documentation of the board's determination in the minutes is sufficient and further signing off is not required.
- 1.2. The results of reviews and actions taken by the IRB via expedited review that grant or may appear to grant Investigators with initial or continuing approval of research, training or educational projects involving human subjects, must be signed off by the IRB Director, the IRB Chair, IRB Vice Chair or IRB member designated by the IRB Chair (i.e. designated expedited reviewer). All results and actions taken by the IRB will be reflected and recorded in ERICA.
- 1.3. For research involving veterans, the IRB will notify the R&D Committee of the VASLCHCS of its decision to approve or disapprove a proposed research activity, or of modifications required to secure IRB approval via notification from the ERICA system. Notification will be a copy of the investigator's approval letter, or a copy of the IRB minutes with the actions of the IRB. Approval letters will be sent by ERICA and received by the VASLCHSC Research Compliance Officer or designee. IRB minutes are made available within 3 weeks of the meeting date and accessible by the VASLCHSC Research Compliance Officer or designee.
 - 1.3.1. Projects which are classified as exempt from IRB review and involve veterans must be reviewed by the R&D Committee prior to initiation. The exempt status must be approved by the IRB Chair, IRB Vice Chair, or IRB member designated by the IRB Chair.

2. Routine Internal Correspondence

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 staff which do not imply or appear to imply approval of this activity, may be signed by designated IRB staff members.

3. Correspondence with External Agencies

Any letters, memos or emails sent to agencies of the federal government, funding agencies (whether private or public) or their agents will be signed by the Institutional Official, IRB Director or IRB Chair or designee.

4. Decisions Made by Chairperson

Any letters, memos or email sent representing the decision or opinions of the IRB Chair or his/her respective designees, as long as such correspondence does not imply review and approval of research projects, may be signed by designated IRB staff.