

Approved by IRB Executive Committee: January 14, 2009  
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 AAHRPP Element I.2.B., II.8.A.

**DEFINITIONS**

- a) Affiliated Institutions**      Affiliated institutions have a Memorandum of Understanding with the University of Utah designating the University of Utah IRB as the IRB of record. The University of Utah IRB has oversight over research conducted at affiliated institutions. A list of affiliated institutions is posted on the IRB web site.
- b) Cooperative Research Projects**      Cooperative research projects involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable regulations.
- c) External Institution**      The University of Utah IRB defines an external institution as:

  - engaged in research
  - does not have a Memorandum of Understanding with the University of Utah and;
  - is not part of the University of Utah or the University of Utah Health Sciences Center, including Associated Regional & University Pathologists (ARUP), Eccles Institute of Human Genetics, Huntsman Cancer Institute, Moran Eye Center, and all other centers and clinics managed by University Health Care and all main campus departments
- d) Unaffiliated Investigator**      An investigator who is not faculty, staff or a student at the University of Utah or its affiliated institutions. For a complete description of who can be a principal investigator at the University of Utah, see the IRB website.

**POLICY**

The University of Utah IRB, with the approval of the Institutional Official, may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Federal-wide Assurance agreements (FWA).

**University of Utah IRB Review for External Institutions:** The University of Utah IRB may review and approve a research project conducted at an External Institution. This

decision will be made on a case-by-case basis by the University of Utah IRB (with the approval of the Institutional Official) in conjunction with the External Institution.

In order for the University of Utah IRB to consider becoming the IRB of record for a research project conducted at an External Institution, all requirements must be met as outlined on the IRB website. The External Institution must enter into any applicable agreements (e.g. IRB Authorization Agreement, Research Compliance Agreement, HIPAA Assurance) with the University of Utah. Copies of any agreements must be retained by both the University of Utah IRB and the External Institution. The University of Utah retains such agreements electronically in the ERICA system with the research proposal.

**Review by another IRB of Record for Research Conducted at the University of Utah (Facilitated Review by the University of Utah):** If the University of Utah IRB relies on another IRB (i.e., use of a central IRB for cooperative group clinical trials) for research conducted at the University of Utah:

- The University of Utah IRB retains ultimate responsibility for maintaining a human research protection plan including, but not limited to:
  - Safeguarding the rights and welfare of human research participants within the local context.
  - Educating members of the University of Utah's research community to establish and maintain compliance of federal regulations and institutional policies relevant to human research participants.
  - Implementing appropriate oversight mechanisms, within the local context, to ensure compliance with the determinations of the reviewing IRB.
- Respective responsibilities of the University of Utah IRB and the IRB of record must be put in writing. The agreement will document, at a minimum, the following items:
  - Role and responsibility of the IRB of record;
  - The authority of the IRB of record to oversee the study;
  - The responsibility of the IRB of record for oversight and continuing review.
- The University of Utah IRB will modify the current federal wide assurance by adding the IRB which will be the IRB of record for research conducted at the University of Utah.

The IRB Director, IRB Chair and Institutional Official will evaluate the adequacy of the proposed IRB in light of the scope and purpose of the research, as well as the participant populations likely be to involved, the appropriateness of initial and continuing review in light of probable risks, and the size and complexity of the institution. The proposed IRB is evaluated to ensure policies and procedures are in place which provide arrangements for communication with participating sites in order to provide sufficient knowledge of the conditions surrounding the conduct of the research, and to ensure that risks to subjects are minimized and assure that the IRB of record will be made aware of unexpected problems in a timely manner.

The IRB Director, IRB Chair and Institutional Official make the final decision of whether to enter into an agreement allowing for another IRB to review research conducted at the University of Utah. Copies of any agreements must be retained by both the University of Utah IRB and the External Institution. The IRB Director or designee is responsible for maintaining copies of such agreements.

**Review by another IRB of Record for a Single-Project:** If a research project is conducted entirely at an External Institution it may still require University of Utah IRB approval (e.g. University of Utah faculty is an investigator, etc.). If the research is no more than minimal risk and there is an IRB at the External institution, the University of Utah IRB (with the approval of the Institutional Official) may allow the External Institution's IRB to be the IRB of record for the single project. This will be addressed on a case-by-case basis. The University of Utah must enter into an IRB Authorization Agreement with the External Institution in order for this to occur. Copies of any agreements must be retained by both the University of Utah IRB and the External Institution. The IRB Director or designee is responsible for maintaining copies of such agreements.

**Research Activities Conducted at the University of Utah by Unaffiliated Investigators:** The University of Utah IRB will acknowledge recruitment of subjects for research conducted by an unaffiliated investigator at the University of Utah (or an affiliated institution) when:

- The University of Utah IRB does not act as the ethical review board; and
- Research activities are not conducted at the University of Utah (or an affiliated institution).

The University of Utah IRB will defer the approval process of recruitment of subjects only to the specific University Department or department head/authority. If the unaffiliated investigator wishes to conduct recruitment AND research activities at the University of Utah (or an affiliated institution), the University of Utah IRB requires that the unaffiliated investigator obtain an affiliated faculty sponsor at the University of Utah who will act as the principal investigator at the University of Utah. A complete research application for review and approval is required before any recruitment or research activities occur.