

SOP 409: ALTERNATIVE IRB REVIEW ARRANGEMENTS AND AGREEMENTS

PURPOSE

The University of Utah Institutional Review Board (IRB) may enter into alternative IRB review arrangements and agreements to provide the ethical review of multiple sites. The University of Utah may also rely upon the review of another IRB. This policy outlines the procedures to execute such agreements.

SCOPE

This policy applies to non-exempt human subject research.

DEFINITIONS

- A. For the purposes of this policy, **affiliated institutions** are defined as having a Memorandum of Understanding (MOU) 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. The University of Utah IRB defines an **external institution** as an institution engaged in research which is outside of the University of Utah and is not affiliated with the University of Utah.
- C. A **Human Subjects Protection Program (HRPP) review** is the process an institution uses when determining whether to accept the review conducted by an external IRB. A facilitated review is not a convened IRB review and does not issue IRB approval. Rather, a facilitated review accepts and relies on the approval issued by an external IRB, central IRB (CIRB) or single IRB (SIRB). This may also be called a “facilitated review”.
- D. A **lead investigator** is one who oversees the operations of the study at the lead site and is ultimately responsible for coordination, management, reporting, and regulatory requirements between multiple sites.
- E. A **lead site** is one that initiates or manages a research study involving multiple sites that conduct research procedures for the study.
- F. A **multi-site study** uses the same protocol to conduct non-exempt human subjects research at more than one site.
- G. A **participating site** in a multi-site study is a domestic entity that will rely on the SIRB to carry out the site’s initial and continuing IRB review of human subject research for the multi-site study.

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- H. The **reliance agreement** documents the respective authorities, roles, responsibilities, and communication between the institution/organization providing the IRB/ethical review and a participating site relying on the SIRB.
- I. The **Single Institutional Review Board (SIRB)** is the IRB of record that has been selected to carry out the IRB review requirements at 45 CFR Part 46 for participating sites of the multi-site study. This may also be called “single IRB”, “central IRB”, or “CIRB”.
- J. An **unaffiliated investigator** is 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 Institutional Review Board (IRB) is the IRB of record for all research conducted at the University of Utah. The University of Utah encompasses the Huntsman Cancer Institute, Moran Eye Center, and all other centers, laboratories, and clinics managed by University of Utah Health and all main campus departments. Associated Regional & University Pathologists (ARUP) and Community Nursing Services (CNS) are nonprofit corporations wholly controlled by the University of Utah. The University of Utah IRB is the IRB of record for research involving ARUP and CNS.

The University of Utah, with the approval of the Institutional Official (IO), may agree to joint IRB 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) as necessary.

The University of Utah IRB and the University of Utah Human Research Protection Program (HRPP) work together to ensure that the University of Utah adheres to all applicable federal regulations, state laws, and institutional policies when using joint and alternative IRB review arrangements. University of Utah IRB staff members provide primary oversight of the process for alternative IRB arrangements and negotiation of reliance agreements. The Institutional Official has authority to enter into master reliance agreements. Once executed, the IRB Director has the authority to accept and confirm the reliance for any individual projects subject to a master reliance agreement.

University of Utah IRB Performing Review for External Institutions

The University of Utah IRB may review and approve a research project conducted at an external institution. The University of Utah IRB adheres to the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. As such, the University of Utah IRB may be a reviewing SIRB for domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research.

Prior to the University of Utah IRB agreeing to become the IRB of record for a research project conducted at an external institution, including becoming the SIRB for a multi-site study, a reliance consultation will take place. The external institution must enter into a reliance agreement with the University of Utah and provide any requisite documents to the University of Utah IRB including any local

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context information, as necessary. Agreements will specify the type(s) of research, or the individual research project conducted under the agreement and outline the duties and responsibilities of the University of Utah IRB and the external institution/investigator.

Copies of any agreements and any accompanying documentation must be retained by both the University of Utah IRB and the external institution. The University of Utah IRB retains such agreements electronically in the ERICA system with the research proposal or in the University of Utah HRPP Electronic Agreement System (EMMA) or another electronic system where the agreement originated (e.g., SMART IRB).

Relying on the Review by an External IRB for Research Conducted at the University of Utah

If the University of Utah relies on another IRB (i.e., use of a central IRB for cooperative group clinical trials or ceding review to a Single IRB) for research conducted at the University of Utah:

- The University of Utah 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. The University of Utah IRB retains the responsibility to maintain oversight for local unanticipated problems involving risks to participants or others and non-compliance. The University of Utah IRB retains the authority to conduct audits to ensure compliance.
 - Conduct conflict of interest review for University of Utah investigators.
 - Educating members of the University of Utah’s research community to establish and maintain compliance with 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 HRPP 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.

Prior to ceding review to another IRB of record, a reliance consultation will take place considering the adequacy of the proposed SIRB considering the scope and purpose of the research, as well as the participant populations likely to be involved, the appropriateness of initial and continuing review considering 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 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 University of Utah IRB reliance agreement Staff 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 are signed by the University of Utah’s Institutional Official and must be retained by both

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the University of Utah HRPP and the external institution. The University of Utah IRB reliance agreement staff is responsible for ensuring copies of such agreements are retained in the University of Utah IRB Agreements system or another electronic system where the agreement was originated (e.g., SMART IRB).

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.

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