Human Research Protection Program Departmental Policy and Procedure

1.6 Reliance on Non-UT Southwestern IRB

Effective Date: August 31, 2026

I. Policy Statement

a. UT Southwestern investigators frequently collaborate in research involving external investigators and institutions.

b. When non-exempt human participant research is being conducted in collaboration with other institutions or with collaborating individual investigators, each collaborating institution and/or collaborating individual investigator engaged in the research must obtain IRB approval from an appropriately authorized IRB.

c. The OHRP guidance document, Guidance on Engagement of Institutions in Human Subjects Research will be used as the basis for determining whether the research activities constitute engagement in human participant research. Such determinations will be made in collaboration and consultation with authorized representatives of the collaborating institution and/or the collaborating individual investigators, as applicable.

d. To reduce duplicate submission and oversight by multiple IRBs for the same protocol, the UT Southwestern Medical Center HRPP will consider requests to rely on another institution's IRB.

e. The Institutional Official (IO), in consultation with Legal Affairs, Assistant Vice President for Human Research Administration (AVPHRA), and the Institutional Review Board Director (IRBD) has the authority to execute IRB Authorization Agreements (IAAs) on behalf of the UT Southwestern Medical Center. All determinations to rely upon another IRB shall be documented in an IAA or reliance agreement (RA).

II. Scope

a. This policy applies to all human subjects' research in which UT Southwestern IRB has agreed to rely on the review of a non-UT Southwestern IRB.

III. Procedures For Policy Implementation

a. Requesting Reliance

b. Investigators considering requesting reliance on another IRB should contact the HRPP Department (HRPPD) early in the research proposal process. Decisions about whether to permit reliance on another IRB shall be determined by the IO, after review and recommendation by the AVPHRA or IRBD.

c. UT Southwestern Medical Center may rely on another appropriately constituted IRB for the review of cooperative research projects under the conditions set forth below.

d. In deciding whether or not to rely on another IRB, the IO will consider the following criteria:

   i. Whether the use of a Central IRB mechanism has been mandated by the study sponsor, NIH Policy, 2018 Common Rule,

   ii. The number of proposed studies involved in the collaboration,

   iii. The anticipated level of risk associated with proposed studies,

   iv. The terms and conditions of the proposed IAA or RA,

   v. Whether the reviewing IRB's policies and procedures meet UT Southwestern Medical Center standards. If the other IRB is AAHRPP accredited, then it will be presumed that the UTSW standards are being met; if the other IRB is not AAHRPP accredited, the HRPP will request the other IRB complete the AAHRPP IRB Evaluation Checklist; accredited status does not in itself necessarily suffice as a basis for the IO's decision,

   vi. The location where the human research activities will take place,

vii. The capacity of the other institution and its IRB to sufficiently be informed about the UTSW local research context and applicable laws and regulations,

viii. Whether or not the reviewing IRB will be serving as the HIPAA Privacy Board.

e. Executing IRB Authorization Agreements

i. In order to initiate discussions with the institution requesting the reliance agreement, the UTSW investigator must provide the HRPP Reliance Program Manager with:

1. contact information for the collaborating institution's IRB,
2. a draft version of the protocol and consent form, and
3. copy of the local context form (if applicable).

ii. The AVPHRA, IRBD, HRPP Reliance Program Manager or his/her designee will ensure that the finalized agreement is appropriately signed by the IOs for the involved institutions. Copies of all agreements will be maintained in the HRPPD electronic filing system.

iii. These agreements may include, but are not limited to, the SMARTIRB agreement. If the reviewing IRB is unable or unwilling to sign the joinder, the UTSW HRPP will review the reviewing IRB's template IAA.

iv. When relying on another IRB, UTSW will ensure that any written agreement will describe the role of each organization, including but not limited to:

1. Providing education to researchers and research staff.
2. Conducting scientific review.
3. Ensuring concordance between any applicable grant and the IRB or EC application.
4. Reviewing potential noncompliance, including complaints,

protocol deviations, and results of audits:

a. Identifying which organization is responsible for deciding whether each allegation of noncompliance has a basis in fact.
b. Identifying which organization's process is used to decide whether each incident of noncompliance is serious or continuing.
c. Obtaining management plans for researcher and research staff conflicts of interest. If the relying organization maintains responsibility for this issue, the management plan must be provided to the IRB or EC in a timely manner prior to the decision by the IRB or EC.

5. Managing organizational conflict of interest related to the research.
6. Ensuring that, should termination of a reliance agreement occur, one of the parties clearly is responsible for continued oversight of active studies until closure or a mutually agreed upon transfer of the studies.
7. A description of which organization is responsible for meeting additional certification requirements, such as Certificates of Confidentiality or the NIH Genomic Data Sharing Policy.

f. ETHOS Submission

i. In order to maintain an accurate record of studies being conducted at or by UTSW and affiliates, as well as to manage required ancillary reviews, investigators are required to create an eIRB application utilizing the external pathway for studies that are reviewed by another IRB.

ii. Updates to the ETHOS application are required

1. at the time of continuing review (within 30 days of the IRB of

Record's reapproval),

2. if there is a change in local (site) PI or other local study personnel,
3. if there is a change that affects any of the required ancillary reviews,
4. if there is a change to the consent form which will require acknowledgment by HRPPD Reliance Team,
5. any other changes to the protocol or documents to ensure the most up-to- date protocol records in ETHOS, and
6. New reports of local events that meet the local UPIRSO and UADE or Noncompliance review policies.

g. HRPPD Reliance review

i. Investigators are encouraged to meet with HRPPD Reliance Team prior to submission

ii. HRPP Reliance will review the following before accepting the IRB of Record's review of the research for UTSW and/or affiliates:

1. Training is completed according to 5.2 Research Education And Training.
2. Management plans issued by the COI Office. The COI Office ensures that training and financial disclosures are completed according to applicable institutional policies.
3. Ancillary committee (e.g., Protocol Review and Monitoring Committee) and other safety committee approvals (e.g., IBC, Radiation Safety, etc.) were received as appropriate.
4. Confirmation of approval by the IRB of Record that UT Southwestern and/or affiliates is/are approved as a study site(s).
5. The informed consent document contains all locally required elements:

a. Research-related injury language consistent with UTSW template
b. Contact information in the consent or related documents (as appropriate) for local investigators and HRPD
c. Radiation and risk language consistent with approved template language

h. HRPP Acceptance to Begin Research

i. All research conducted at/by affiliates of UTSW must also receive approval from affiliate research administration offices.

ii. A member of the HRPP Reliance Team will acknowledge receipt of the information and accept the study at UT Southwestern.

iii. Upon initial acceptance and after any modifications to consent forms, the informed consent forms will be stamped with the HRPP Acceptance Date to assist with version control.

i. Modifications

i. External IRB Modifications resulting in changes to the local site application when UT Southwestern IRB is not the IRB of record must be approved by the Human Research Protection Program Department (HRPPD). Examples include (but are not limited to): study staff changes, changes to COI management plans, safety committee approvals, local contact information in consent document, HIPAA language or waiver requests. (See 1.6. RELIANCE ON NON-UT SOUTHWESTERN IRB.)

IV. Definitions

a. See Glossary of Human Research Terms

V. References

a. 21 CFR 50: Protection Of Human Subjects,

b. 45 CFR 46 – Protection Of Human Subjects,

c. 45 CFR 164 – Security And Privacy (HIPAA Privacy Rule),

d. 21 CFR 56 – Institutional Review Boards,

e. OHRP Guidance – Engagement Of Institutions In Human Subjects Research (2008),

f. NIH sIRB Policy – Final NIH Policy On The Use Of Single Institutional Review Board For Multi-Site Research

VI. Revision and Review History

a. June 2026; HRPP; Replaced references to eIRB with ETHOS

b. November 2021; HRPP; Updated requirements for relying on non-AAHRPP accredited institutions, defined that UTSW may use SMART IRB or another IAA, and defined requirements for all IAAs

c. June 2021; HRPP; Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

d. August 2017; HRPP; New Policy Development

e. March 2012; IRB Office; IRB Written Procedures