Human Research Protection Program Departmental Policy and Procedure

2.8 Collaborative Research Involving External Investigators/Institutions Reviewed by UTSW IRB

Responsible Office: Human Research Protection Program Department (HRPPD)

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 for other institutions and individual investigators to rely on UTSW for IRB review.

e. The Institutional Official (IO), in consultation with Legal Affairs and 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 for another institution to rely on UTSW IRBs shall be documented in an IAA or reliance agreement (RA).

f. When the NIH has given an exception from single IRB review for a multi-site NIH funded study, and when UTSW is the primary award holder, the rationale for not relying upon a single IRB review (in accordance with NIH policy on exceptions from single IRB review) will be documented for that study in the ETHOS system.

g. For Investigators who are not affiliated with an assured institution, an Individual Investigator Agreement (IIA) may be signed to extend the UTSW assurance to cover that individual. The IO or designee in consultation with the Principal Investigator's Department Chair, has the authority to extend the UTSW FWA for individual investigators on a study-by-study basis.

II. Scope

a. This policy applies to all human subjects' research in which UT Southwestern IRB has agreed to review research on behalf of another assured institution or non-assured individual investigators.

III. Procedures for Policy Implementation

a. Requesting Reliance on UTSW IRB

i. Investigators considering collaboration with another assured institution who wish to utilize UTSW IRB for non-UTSW affiliated sites should contact the HRPP Department (HRPPD) early in the research proposal process. Decisions about whether to permit another institution to rely on UTSW shall be determined by the IO, after review and recommendation by the AVPHRA or IRBD.

ii. UT Southwestern Medical Center may accept another institution to rely on UTSW IRBs for the review of cooperative research projects under the conditions set forth below.

iii. In deciding whether or not to provide IRB review for another institution, the IO will consider the following criteria:

1. The number of studies being proposed under the agreement,
2. the number of sites engaged in the research,
3. the risk level of the study,
4. whether the study is being conducted under an investigator-initiated IND or IDE,
5. the location where the interventional human research activities will take place,
6. whether the use of a Central IRB has been mandated by the sponsor, NIH Policy, 2018 Common Rule,
7. whether adequate funding is provided to cover the additional costs associated with managing the approval and necessary IRB oversight at the other sites, and
8. UT Southwestern's capacity to be sufficiently informed about the other
9. institution's local research context and local applicable laws and rules.

iv. Executing IRB Authorization Agreements

1. In order to initiate discussions with the relying institution, the UTSW investigator must provide the HRPP Reliance Program Manager with:
   a. contact information for the collaborating institution's IRB,
   b. a draft version of the protocol and consent form, and
   c. copy of the local context form (if applicable).
2. 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.

3. These agreements may include, but are not limited to, the SMARTIRB agreement. Relying sites are encouraged to sign the joinder to SMARTIRB. However, if relying sites are unable or unwilling to sign the joinder, the UTSW HRPP can execute UTSW's template IAA with an individual site.
4. When serving as an IRB for another institution, UTSW will ensure that any written agreement will describe the role of each organization, including but not limited to:
    a. Providing education to researchers and research staff.
    b. Conducting scientific review.
    c. Ensuring concordance between any applicable grant and the IRB or EC application.
    d. Reviewing potential noncompliance, including complaints, protocol deviations, and results of audits:
        i. Identifying which organization is responsible for deciding whether each allegation of noncompliance has a basis in fact.
        ii. Identifying which organization's process is used to decide whether each incident of noncompliance is serious or continuing.
        iii. 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.
    e. Managing organizational conflict of interest related to the research.

f. 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.

g. A description of which organization is responsible for meeting additional certification requirements, such as Certificates of Confidentiality or the NIH Genomic Data Sharing Policy.

h. Determining which organization is responsible for obtaining any additional approvals, certifications, or determinations required by HHS when the research involves pregnant women, fetuses, neonates, children, or prisoners, including compliance with the requirements of 45 CFR 46 Subparts B, C, and D.

b. ETHOS Submission

i. In order to maintain an accurate record of studies being conducted at or by UTSW and affiliates, as well as all relying sites, investigators are required to update the ETHOS Smart Form to list the relying site.

1. Relying research sites will be added during initial review or as modifications to the approved study.

2. When reviewing modifications to add relying sites, the IRB will follow the requirements of 2.3 MODIFICATIONS TO RESEARCH with regard to whether the changes reflect a major a minor modification. Generally, the addition of a relying site and supporting documents will be considered a minor modification unless the relying site requires significant changes to the study design (including but not limited to consideration of new/increased risks, changes in use of drugs, new vulnerable populations, etc.) due to local considerations.

ii. The completed reliance agreement, local context form, and site specific consent document (if applicable) must be uploaded to the ETHOS system.

c. IRB Review

i. Review and approval of the research will commence according to 2.1. Initial Review Of Research, 2.2. Continuing Review Of Research and 2.3 Modifications To Research policies.

d. IRB Knowledge of Local Regulatory Issues

i. In accordance with OHRP guidance, when UT Southwestern IRB serves as the Reviewing IRB for another institution or when the research involves distinct subject populations (non-English speaking populations, veterans, etc.), UT Southwestern IRB ensures that it possesses or obtains sufficient knowledge of the local regulatory issues even when the IRB is geographically removed from the off-site research location.

ii. Additionally, in accordance with FDA requirements, an IRB may review studies performed at off-site locations as long as the requirements for 21 CFR parts 50 and 56 are met. In these cases, a written agreement, which the local IRB or the administration of the institution signs, allows review by a non-local IRB.

iii. Review of the proposed research by one or more ad hoc or cultural consultants with knowledge of the local regulatory issues. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review, either physically or through audiovisual or telephone conference, when participation is deemed warranted by the consultant(s) or any one member of the IRB;

iv. Systematic reciprocal documented interchange between the IRB and elements of the local regulatory issues through periodic visits to the research site, occurring several times per year, by one or more IRB members in order to obtain and maintain knowledge of the local regulatory issues; periodic discussion with appropriate consultants knowledgeable

about the local regulatory issues; regular interaction with one or more designated institutional liaisons; and/or review of relevant written materials;

v. Site visit by a representative of the IRB;

vi. Appointment of an IRB member from the community in question.

vii. The research staff assists the PI in addressing the requirements for information on the local regulatory issues upon request.

viii. The research staff assists the IRB in identifying appropriate consultants and distributing appropriate review materials pertaining to the local regulatory issues to IRB members, as appropriate.

ix. The research staff maintains documentation in the database and the study file of the local regulatory issues and the measures taken to ensure sufficient IRB knowledge of that context.

x. The IRB includes the name and contact information for an IRB contact in the consent document for non-local IRB review or designates an individual at the research site to serve as the contact to relay reports to the IRB.

xi. In the minutes of the meeting during which non-local research review occurs, research staff document the procedures used to ensure that the IRB adequately considered community attitudes.

e. Non-Assured Sites

i. UTSW HRPP will first consider whether the non-assured site should obtain an FWA

1. OHRP notes that if HHS-conducted or supported human research activities routinely occur at non-assured institution, the institution should obtain an OHRP approved FWA.

2. If the Non-Assured institution is the prime awardee for HHS supported

award, the institution must obtain its own FWA.

3. If the institution must obtain an FWA, then an IRB Authorization Agreement (IAA) as described above would be executed with the site or the institution would obtain another IRB review.

ii. If the Non-Assured Site will not obtain an FWA, the UTSW HRPP will consider whether an Individual Investigator Agreement (IIA) is appropriate as described below.

iii. For non-affiliated, non-assured sites that are not engaged in research, the UTSW IRB will request a letter of support from the performance site when applicable.

f. Cooperative Research Involving Off-Site International locations engaged in research

i. Collaborative research activities at off-site international locations that are funded or supported by HHS must be conducted under an active international assurance issued by the Office for Human Research Protections. International collaborative research that is not funded or supported by HHS should be conducted under applicable national or international procedural standards that are at least as stringent as the requirements of 45 CFR part 46.

ii. The PI arranges for the international site IRB (or equivalent entity) to review the research and submit official correspondence addressing the following information:

1. For HHS funded or supported research, the international site's International FWA number and the appropriate IRB approval from the assured institution's designed IRB (including the OHRP registration number for the IRB/IEC).

2. For non-HHS funded or supported research, the appropriate IRB (or

equivalent entity) approval.

3. Cooperative Research Involving Off-Site International locations not engaged in research. Follow procedures for local institutional approval to conduct research at the site.

iii. All policies and procedures applied to domestic research are also applied to research conducted at international research site.

1. Initial Review, Continuing Review and review of modifications (see Initial Review of Research Policy and Procedure, Continuation Review Policy and Procedure, Modification and Amendments Policy and Procedure)

2. Handling Complaints, Noncompliance, and Unanticipated Problems

3. Informed consent process (including language issues). See Informed Consent Policy and Procedure.

g. Serving as IRB of Record for non-affiliated Investigators

i. UTSW may choose to extend the Federalwide Assurance (FWA) to cover research activities by engaged non-UTSW investigators who work for non-assured (FWA) institutions.

ii. Researchers collaborating with a non-assured individual should contact the HRPPD Reliance Program Manager to discuss inclusion of the individual on the research. The individual may be added to a research protocol by utilizing one of the following methods:

1. The PI research department may request Contingent Worker (CWR) status for the individual (preferred).

a. This is required if the individual will be engaged in research at UTSW.

2. An Individual Investigator Agreement (IIA) may be signed if the

individual is engaged in human subjects' research and the following apply:

a. The institution the individual works with does not wish to obtain an FWA, and

b. The research activities will not be conducted at UTSW.

iii. When a non-affiliated investigator is identified, the PI should contact the HRPPD to determine the appropriate method for covering the individual

iv. The non-affiliated individual must be added to the ETHOS Smart Form.

v. When an individual is covered by UTSW FWA (either via IIA or CWR status), the investigator must comply with all UTSW investigator requirements (e.g., CITI human subjects training, COI training and COI disclosure).

IV. Definitions

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

VI. Revision and Review History

a. Revision Date: August 2026; Author: HRPP; Description: Added an additional definition for the responsibilities of the relying organization

b. Revision Date: June 2026; Author: HRPP; Description: Reference to eIRB updated to ETHOS

c. Revision Date: November 2021; Author: HRPP; Description: Updated to

address documentation of exceptions for NIH sIRB policy in eIRB, requirements for IAAs, and that UTSW will use the SMART IRB or another IAA template

d. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

e. Revision Date: June 2018; Author: HRPP; Description: Addition of IRB Knowledge of Local Regulatory Issues section

f. Revision Date: August 2017; Author: HRPP; New Policy Development

g. Revision Date: March 2012; Author: IRB Office; IRB Written Procedures