Human Research Protection Program Departmental Policy and Procedure Manual

0.0 About the Human Research Protection Program Department

Effective Date: May 28, 2026

I. Overview

a. The University of Texas Southwestern Medical Center has assured the US Department of Health and Human Services (DHHS) of compliance with DHHS regulations (45 CFR § 46.103) for the protection of human subjects, through an Office of Human Research Protection (OHRP) approved Federalwide Assurance (FWA00005087).

b. The Institutional Review Board (IRB) Director serves as the Human Protection Administrator (HPA) and is responsible for maintaining the FWA records and documentation.

c. The HRPP Department (HRPPD) maintains the Federalwide Assurance and IRB membership roster with OHRP.

II. Executive Leadership of the HRPP

a. The UT Southwestern President formally designates the Institutional Official according to RES- 151 Human Research Protection Program.

b. Review and management of inappropriate influence of the IRB, IRB Members and HRPP staff

i. The UT Southwestern Medical Center grants the IRBs the authority to act independently to bind all activities falling under the IRB authority (see Institutional Policy RES-151). All UTSW personnel who become aware of attempts to inappropriately influence the IRB, IRB Members or HRPP Staff are to report such incidents to the IRB Diretor or Associate Vice President for of Research Regulatory Affairs (AVPRRA)AVPORRA, who notifies the Institutional Official (if allegations involve the IRB Director, AVPRRA or IO, then the Provost will be notified). The IO in consultation with the IRB

Director and/or AVOPRRA and other appropriate institutional officials will evaluate the allegation. If the allegation is validated they will determine the appropriate response and any action required will be taken by at least a department level supervisor. Responses may range from an oral or written reprimand up to and including suspension of the individual from some or all current or future research activities under the review of the UTSW IRBs. The IO may refer the issue for additional institutional action.

III. HRPP Department Administration

a. Policy Development

The IRB Director along with the AVPORRA develops and implements written HRPP policies and procedures under applicable regulations for the protection of human subjects.

b. Knowledge, Skills and Abilities of HRPPD staff

The Associate Vice President for Research Regulatory Affairs, IRB Director (IRBD), IRB Assistant Director and Program Managers, and staff must be familiar with the ethical principles guiding human research; the requirements of federal regulations, applicable state law, the institution's FWA; and, institutional policies and procedures established for the protection of human subjects.

c. HRPPD Responsibilities

i. Managing IRB operations and regulatory review under the leadership of the IRB Director. This includes all activities necessary to maintain an IRB such as:

1. Pre-review all submissions to ensure consistency and completeness. The pre- review will also ensure the IRB has enough information to make the required regulatory decisions.

2. Managing IRB meetings:

a. Creating agendas and assigning IRB reviewers

b. Assembling and sending IRB materials

c. Ensuring quorum will be present and maintained

d. Tracking IRB member attendance

3. Manage membership rosters,

    a. Manage updates to rosters with Institutional Official (IO)

    b. Send membership letters to members

    c. Maintain current OHRP membership rosters

4. Preparation and finalization of IRB minutes

5. Recording and reporting IRB decisions

6. Maintaining IRB records

7. Ensure research maintains compliance with institutional policies and the UTSW Federalwide Assurance (FWA):

    a. Assuring and warranting that all investigators participating in the approved research are and will remain members of the Institution's staff in good standing and are credentialed and privileged to perform the procedures outlined in the studies.

    b. Assuring that all UTSW investigators comply with the UTSW investigator ethics education requirements and other human research related training/education requirements and policies.

    c. Prior to study activation, conducting additional administrative reviews as determined by the UTSW Institutional Official and UTSW policy to include the following:

        i. Ensuring all other institutional committee reviews and approvals are secured (Subcommittee for Human Use

Radiation, Institutional Biosafety Committee, Protocol Review and Monitoring Committee, Laser Committee, etc.)

ii. Ensuring funding, billing plans, and payments to participants are in place and Medicare coverage analysis are completed, if applicable

iii. Ensuring the research site is adequate for procedures purposed in the protocol and assessing the potential impact on clinical services

iv. Ensuring all HIPAA and data security requirements are being met

v. Assessing Conflict of Interest (COI) management plans approved by the COI Committee, and recommending additional requirements, if applicable

vi. Notification and coordination with affiliated sites for the proposed research

8. Managing reviews of research involving reliance on non-UTSW IRBs under the leadership of the IRB Director. In addition to the responsibilities outlined in 8 above, additional reliance responsibilities include:

    a. Establishing and managing all signed IAAs/MOUs and ensuring compliance with the requirements agreed upon by the external IRB and UTSW.

    b. Ensuring a mechanism for appropriate reporting to the external IRB of the following events:

        i. Termination, suspension, or modification of any clinical privileges of members of its Staff who are

participating in the studies authorized by the external IRB.

ii. Unanticipated problems involving risks to subjects or others; or any serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s) identified by the institution.

iii. Any contact by the FDA, HHS, or any other persons or entities regarding any of the research approved by the external IRB. UTSW will also notify the external IRB office in the event that the FDA or other governmental agency issues the institution any “Notice of Inspectional Observations,” “Warning Letters,” or other communications citing improper or inadequate research practices with respect to the research approved by the external IRB.

9. Maintain all HRPP and IRB records as required by federal regulation and institutional policy

ii. Quality assurance and monitoring

1. Investigate allegations of non-compliance with institutional policies or research regulations for the protection of human subjects and reports of unanticipated problems.
2. Conduct regular not-for-cause audits of research studies.
3. Conduct for-cause audits of research studies where allegations arise or where the IRB or IO requires the audit.

iii. Regulatory Support

1. ClinicalTrials.gov

a. Supports research teams with navigating and complying with the requirements of ClinicalTrials.gov.

b. Provides guidance in determining whether a clinical trial must be registered, who is responsible for the registration, when the registration must be updated, and whether study results must be reported.

c. Assists with understanding the deadlines and requirements for registration, updates, and results reporting.

2. Sponsor Investigator Support

a. Provides guidance on whether an IND is required; answers questions about the submission process; and assists researchers in complying with the regulatory requirements associated with IND and IDE applications.

b. As needed, will reduce the administrative burden on investigators by maintaining, managing, and monitoring INDs and IDEs; assisting with development of data and safety monitoring plans; assisting with the renewal of applications; and writing and submitting annual progress reports.

iv. Participant Advocacy

1. Offers consulting expertise on human subjects and regulatory issues, IRB applications, the informed consent process, study feasibility and good clinical practice (GCP).

2. Serves as a resource to research participants by taking calls, concerns, complaints, and answering questions about participation in research. Our team

3. is also available to assist research teams by reviewing consent

forms, protocols or data and safety monitoring plans.

IV. Institutional Review Board

a. Authority of the IRB

i. The University established the IRB in accordance with the Institutional Policy RES-151 “Human Research Protection Program”. The UTSW grants its IRBs the authority to:

1. Approve or require modifications to secure approval or disapprove all research activities overseen and conducted by the organization.
2. To suspend or terminate approval of research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected harm or increased risk to participants.
3. To observe, or have a third party observe, the consent process.
4. To observe, or have a third party observe, the conduct of the research.

ii. In addition, the IRB will review noncompliance and unanticipated problems, in cases where corrective actions are needed, the IRB may take appropriate actions, to include, but not limited to, requiring modifications, determining data collected cannot be used for publication, suspending or terminating approval, requiring additional education, disqualifying investigators from conducting research.

b. Knowledge, Skills and Abilities of IRB Members

The IRB Chairs and members (primary, alternate, and ex officio) must be familiar with the ethical principles guiding human research; the requirements of federal regulations, applicable state law, the institution’s FWA; and, institutional policies and procedures established for the protection of human subjects. The IRB as a whole must also have effective knowledge of subject populations and other factors which can potentially contribute to a determination of risks and

benefits to subjects and which can impact participants' informed consent.

c. Removal of IRB Members

Members may be disqualified from the IRB for scientific misconduct, unethical behavior, conflict of interest, or non-compliance with the rules governing the IRB or failure to actively participate. Such concerns are forwarded to the Institutional Official for review and action, as appropriate.

d. IRB Meetings

IRBs meet regularly to review and act on initial and continuing review, as well as review of requests for modification of approved research, reports on non-compliance or unanticipated problems for all non-exempt human research. The IRB Director establishes the schedule for meetings. The IRB Director, IRB Chair, AVPRRA or Institutional Official may direct or convene additional meetings at any time.

e. Challenge of IRB Decisions

i. If a Principal Investigator or other individual/entity has concerns regarding a Designated Reviewer or IRB decision or recommendations for changes in a study, then the individual may submit these concerns to the HRPP Department in writing, including a justification for changing the decision. The request may be sent to the reviewer and/or the IRB Director for final resolution.

ii. If any individual/entity believes the IRB did not have all necessary documentation or information during the original review, he/she/they may request a review of the challenge by the full IRB. The request must include a memo containing justification for changing the decision and any supporting documentation or information the IRB did not have during the original review.

iii. The IRB determination following a review of a challenge is considered final.

V. Communication of Policy Changes to the Research Community

a. Changes to HRPP research policies will be communicated to the research community through official channels, including Research Matters and/or targeted listserv messages, to ensure timely awareness and compliance.

VI. Affiliated Institutions

The UT Southwestern Medical Center IRBs may provide review and continuing oversight of some or all research conducted at affiliated institutions. Institutions relying on the UTSW IRBs remain responsible for ensuring compliance with the IRB's determinations and the terms of its OHRP approved FWA, as applicable.

VII. 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. RES 151: Human Research Protection Program

VIII. REVISION AND REVIEW HISTORY

a. Revision Date: May 2026; Author: HRPP; Description: Role updates and minor clarifications

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

I. Revision Date: May 2019; Author: HRPP; Description: New Development