Human Research Protection Program Departmental Policy and Procedure Manual

1.1 Receiving, Routing, and Administrative Review of IRB Submissions

Effective Date: June 3, 2026

I. Policy Statement

a. All exempt and non-exempt research submissions are submitted in the electronic IRB application system (ETHOS).

b. Submissions are routed to appropriate HRPPD staff and processed by HRPPDD staff in preparation for administrative review, expedited review, or convened IRB review.

c. UT Southwestern IRBs maintain a system of HRPPDD pre-review and scientific & ethical pre- review (as applicable) prior to the review by the expedited reviewer or convened IRB (see 2.1. Initial Review Of Research)

II. Scope

a. This policy and procedures applies to the Human Research Protection Program Department (HRPPD) and UT Southwestern convened IRB's.

III. Procedures for Policy Implementation

a. This procedure starts when a submission to the IRB (new application, modification, continuing review, reportable event, or notice of study closure) is submitted to ETHOS.

b. This procedure ends when any of the following are true:

- The submission is determined to not require IRB review and accepted by the administrative reviewer
- The submission is presented to the Expedited Reviewer
- The submission is presented to the Convened IRB

a. A daily list of all new/unattended submission items in ETHOS are reviewed and

assigned to the regulatory analysts in an equitable fashion.

b. HRPPDD pre-review

   i. The HRPPD Staff will conduct a pre-review using the appropriate checklist for the submission.

   ii. The HRPPD Staff determines whether the submission includes all information required and requests additional information, if needed, from the investigator, to assist the Reviewer or IRB in making a determination.

   iii. The HRPPD staff screen the IRB application to ensure coordination with other university committees or to ensure compliance with pertinent federal requirements. The communication is outlined in the 1.5. Communication With Other Committees And Offices. Examples of screening include, but are not limited to, the items listed below

      1. If PI indicates the research is IND exempt in the application, the appropriate sections of the ETHOS application must be completed. If the investigator omits this information, the HRPPD staff may still continue the pre-review process but request the investigator to send the missing information. In general, the HRPPD staff will not forward the study to a convened meeting without this information.

      2. If the research involves radiation for research purposes, or the investigator otherwise indicates that Radiation Safety Office (RSO) approval is necessary, the information about the radiation must be included in the appropriate sections of the ETHOS application. The HRPPD staff checks to ensure that the PI has submitted the materials. HRPPD staff will not schedule the

application for review and may return the application to the PI if these materials are missing. The investigator may not have obtained RSO approval however, HRPPD staff may check with the Radiation Safety Office (RSO) for advice.

3. For applications indicating one or more of the investigators, employees who are responsible for the design, conduct, or reporting of activities, or their immediate family members have declared a possible conflict of interest, the HRPPD staff will confirm whether the Conflict of Interest Office (COI Office) has issued a management plan. If a conflict of interest management plan has been issued, the HRPPD staff ensure all requirements are met such as screening the consent form for recommended conflict of interest disclosure language.
4. The HRPPD staff screen the application to determine whether the study includes off-site research issues and refers to the procedures outlined in the 2.8 Collaborative Research Involving External Investigators/Institutions Reviewed By UTSW IRB.
5. If the application indicates the research involves prisoners, the HRPPD staff ensures the application contains information about the prisoner population and will ensure a prisoner representative is assigned as an additional reviewer.
6. The HRPPD staff screen the application to see whether the study involves one of the institutional affiliate hospitals. If so, the appropriate institutional research offices may be contacted and included in the HRPPD pre-review process. The institutional research offices staff review is focused on institutional issues (e.g., personnel credentialing, privacy, clinical services, and

institutional policies).

7. If the investigator indicates that the research involves an investigational new drug (IND) or investigational device exemption (IDE), the HRPPD staff confirm the validity of the IND or IDE number by ensuring that a copy (containing the number) of the detailed protocol from the sponsor (may not use the investigator brochure) or other communication from the Sponsor confirming the validity of the IND or IDE number are submitted. Official FDA documents containing the number are also acceptable.
8. HRPPD staff screen the application to determine whether research involves vulnerable subjects and/or sensitive types of research/procedures (e.g., HIV screening). If so, the HRPPD staff notifies the IRB Chair, Expedited Reviewer or Regulatory Specialist who determines whether a consultant needs to be included in the review.
9. The HRPPD staff also screen the application for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, UT Southwestern privacy policies, and Family Educational Rights and Privacy Act (FERPA) issues. If the PI includes a HIPAA authorization form or waiver or if there are any HIPAA or FERPA concerns, the HRPPD staff annotates this for the reviewer in the ETHOS system for expedited reviews or on the IRB Reviewer Worksheet for convened IRB reviews.

iv. The HRPPD staff ensure the submitted forms are on current IRB templates or on the appropriate previously approved forms.

v. HRPPD staff screen the informed consent documents to confirm the

required elements of consent are included. The HRPPD staff will work with the PI/Study Coordinator (SC) to obtain corrected consent form changes(s).

vi. Verify information in the ETHOS system is correct and update information as necessary.

vii. If requested by the IRB Chair, Regulatory Specialist or an IRB reviewer, the HRPPD Staff will send the protocol for a Scientific and Ethical Review or Review by Chair.

1. Scientific/Ethical pre-reviewers complete their reviews and communicate to the HRPPD by a designated deadline.

i. The HRPPD office attempts to make all corrections on the electronic documents; however, the PI/SC may be asked to make substantive changes/additions. If items are missing or require clarification, HRPPD staff will correspond with PI/SC.

ii. If the PI submits a minor modification with a continuing review (CR) application (including annual updates), the HRPPD staff and the IRB follow procedures outlined in the Continuation Review of Research policy, and the HRPPD staff process the modification as part of the CR (See 2.2. Continuing Review Of Research).

iii. The HRPPD staff alert the IRB if changes in the consent form(s) or other pending actions are necessary and HRPPD was unable to obtain the corrected document prior to the IRB review. The IRB may then make a stipulation that the changes be made.

iv. After the pre-review is complete, HRPPD staff will modify ETHOS to route the submission for review as appropriate.

c. Routing for Review (i.e., Administrative, Expedited, or Convened IRB Review)

i. For initial review and modifications, the PI requests the type of review by submitting the appropriate application and, as applicable, checking the appropriate section of the ETHOS Smart Form (e.g., Modification Smart Form, Study application, etc.). The HRPPD staff will confirm or modify the type of review.

v. For continuing review (not including annual updates), the HRPPD staff will route to either expedited or convened IRB review according to the risk level, use of investigational test articles, and any remaining activities on the research study (See 2.2. Continuing Review Of Research).

vi. If the submission qualifies for administrative review (non-human research, non- regulated research, administrative modifications, and annual updates), the HRPPD staff will review the submission and make the final acceptance determination.

vii. If determined to be eligible for expedited review after the administrative pre- review, the submission is routed through the ETHOS system to the Expedited Reviewer.

1. HRPPD staff will document unresolved issues and notes to be forwarded to the Expedited Reviewer in ETHOS.

1. Initial Exempt or Expedited Studies may receive an appointment with an appropriate reviewer if determined necessary by the HRPPD pre-reviewer or Expedited Reviewer.

viii. If determined to require review by a convened meeting of the IRB (full board review) after the administrative review, the submission is routed through ETHOS for the next available IRB meeting.

1. HRPPD staff will document unresolved issues and notes to be forwarded to the Primary Reviewer.

2. The HRPPD staff develops, maintains, and revises the IRB meeting schedule, as appropriate. The schedule of meetings is available on the IRB website or by request.
3. The HRPPD staff creates an agenda in ETHOS, compiles review materials, and notifies the IRB Members and other appropriate individuals scheduled to attend the convened meeting (including alternate members as appropriate) that the materials are available in ETHOS. If special circumstances require adding a protocol to the agenda after it has been sent out, the HRPPD staff modifies the agenda in ETHOS and distributes the applicable application documents (via ETHOS) to IRB members and appropriate individuals prior to the meeting. In addition, the member assigned as the primary reviewer of the study receives the additional materials. There are no limits to the number of agenda items.
4. IRB members receive access to all appropriate study materials, agendas and reviewer assignments with sufficient time (at least five calendar days) for their review prior to scheduled IRB meetings to be prepared to participate in deliberations and voting.

d. After receiving, processing, reviewing and routing for review, the following polices are followed: 2.1. Initial Review Of Research, 6.2 IRB Approval Of Research, 6.3 Conduct Of Full Board Meetings, 8.2 Reporting Policy And Procedure.

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. June 2026; HRPP; Reference to eIRB updated to ETHOS

b. November 2021; HRPP; Defined that there are no limits to full board agendas and the minimum time for documents to be distributed for review

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

d. July 2018; HRPP; Revision to RSO (dissolved SHUR)

e. August 2017'; HRPP; New Policy Development

f. March 2012; IRB Office; IRB Written Procedures