Receiving, Routing, and Administrative Review of UTHSCSA IRB Submissions
Policy and Procedure

I. Policy

a. All submission to IRB are received by the OCR staff, routed to the OIRB staff, and processed by the OIRB staff in preparation for administrative review, Expedited review, or convened IRB review.

b. UTHSCSA IRBs maintain a system of OIRB pre-review and scientific & ethical pre-review (as applicable) prior to the review by the administrative reviewer, expedited reviewer, or convened IRB (see Initial Review of Research Policy and Procedure)

II. Overview

a. This procedure starts when a submission to the IRB (new application, modification, continuing review, prompt report or inactivation) is routed to the OIRB from OCR.

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

   i. The submission is determined to not require IRB review and accepted by the administrative reviewer

   ii. The submission is presented to the Expedited Reviewer

   iii. The submission is presented to the convened IRB

III. Procedure

a. OCR notifies the OIRB of new submissions to the OIRB in the following ways:

   i. An email is sent from OCR notifying the OIRB and affiliates that a new protocol submission has been received and is ready for OIRB review

   ii. The OIRB runs a daily list of all new/unattended IRB items in the IRB Protocol Database tracking system (agenda builder)

b. OIRB pre-review

   i. The OIRB Staff will conduct a pre-review using the appropriate Analyst Coordination Sheet for the submission.

   ii. The OIRB 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 OIRB 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 Coordination with Other Committees or Offices Policy and Procedure. Examples of screening include, but are not limited to, the items listed below
1. If PI indicates the research is exempt from IND in the application, the application must include a completed Drug or Biologic Being Tested in Research form. If the investigator omits this form, the OIRB staff may still continue the pre-review process but request the investigator to send the missing form. In general, the OIRB 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 Committee (RSC) approval is necessary, the RSC worksheet must be included in the IRB application. The OIRB staff checks to ensure that the PI has submitted the materials. OIRB 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 RSC approval however OIRB staff may check with the Radiation Safety Officer (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 completed Protocol Related Conflict of Interest (COI) Report is forwarded to the COI Manager by the OIRB staff to begin that committee’s review process. The OIRB staff screen the consent form (as applicable) for recommended conflict of interest disclosure language.

4. The OIRB staff screen the application to determine whether the study includes off-site research issues and refers to the procedures outlined in the Cooperative Off-site Research Policy and Procedure.

5. If the application indicates the research involves prisoners, the OIRB staff ensures the application contains the Prisoner Form and assigns a prisoner representative as an additional reviewer.

6. The OIRB staff screen the application to see whether the study involves the University Health System, UT Health Science Center, and/or South Texas Veteran’s Healthcare System (STVHCS). The appropriate institutional research offices are contacted and included in the OIRB pre-review process. The institutional research offices staff review is focused on institutional issues (e.g., personnel training and credentialing, privacy).

7. If the investigator indicates that the research involves an investigational new drug (IND) or investigational device exemption (IDE), the OIRB 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) are part of the protocol materials. Official FDA documents containing the number are also acceptable. The OIRB may also require the PI to submit communication from the Sponsor.
containing the title of the protocol, the name of the investigational test article(s), and the IND or IDE number.

8. OIRB 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 OIRB staff notifies the Expedited Reviewer or Regulatory Specialist who determines whether a consultant needs to be included in the review.

9. The OIRB staff also screen the application for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule 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 OIRB staff annotates this on the expedited reviewer worksheet for exempt or expedited reviews or in the IRB protocol database (agenda builder) for convened reviews.

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

   v. OIRB staff screen the informed consent documents to confirm the required elements of consent are included. The OIRB staff will work with the PI/Study Coordinator (SC) to obtain corrected consent form changes(s).

   vi. The OIRB staff screen for HIPAA issues and follow the HIPAA in Research Policy and Procedure (as appropriate).

   vii. Verify information the in IRB Protocol database is correct and update information in agenda builder tracking system.

   viii. If requested by the Chair, Regulatory Specialist or an IRB reviewer, the OIRB 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 OIRB by designated deadline

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

   x. If the PI submits a minor modification with a continuing review (CR) application, the OIRB staff and the IRB follow procedures outlined in the Continuation Review policy, and the OIRB staff process the modification as part of the CR (See the Continuation Review Policy and Procedure).

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

xii. After the pre-review is complete, OIRB staff will modify IRB Protocol Database tracking system (agenda builder) 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 submitted forms (e.g., Amendment Request Form, Common Research Application). The OIRB staff will confirm or modify type of review.

ii. For Continuing review, the OIRB 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 the Continuation Review Policy and Procedure)

iii. If the submission qualifies for administrative review (non-human/non-regulated research, Exempt new protocols), the OIRB will review the submission and make the final acceptance determination.

iv. Administrative modifications may be reviewed and accepted by either the OIRB or OCR staff.

v. If determined to be eligible for expedited review after the administrative review, the submission is routed through the OIRB office to the Expedited Reviewer

1. OIRB staff will document unresolved issues and notes to be forwarded to the Expedited Reviewer

2. Initial Exempt or Expedited Studies may receive an appointment with an appropriate reviewer

vi. If determined to require review by a convened meeting of the IRB (full board review) after the administrative review, the submission is routed through the OIRB office to be scheduled for the next available IRB meeting

1. OIRB staff will document unresolved issues and notes to be forwarded to the Primary and Secondary Reviewers

2. The OIRB staff develops, maintains, and revises the IRB meeting schedule, as appropriate. The dates are available on the IRB website or by request. The OIRB staff schedules the meeting rooms and catering arrangements after confirming the meeting dates.

3. The OIRB staff creates an agenda, agenda packets, 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 on SharePoint. If special circumstances require adding a protocol to the agenda, the OIRB staff prepares a revised agenda and distributes it and the applicable application documents 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.

4. For each meeting, the OIRB staff generates the agenda. The OIRB staff review the agenda for accuracy and completeness before distributing it to the IRB.

5. IRB members receive access to all appropriate study materials, agendas and reviewer assignments with sufficient time for their review at least 5 days prior to scheduled IRB meetings to be prepared to participate in deliberations and voting.

vii. After receiving, processing, reviewing and routing for review, the following policies are followed: Initial Review of Research Policy and Procedure, IRB Approval of Research Policy and Procedure, Conduct of IRB Meeting Policy and Procedure, Reporting Policy and Procedure.

IV. References

Definitions (see Glossary)
Regulatory (see Policy on Policies Policy and Procedure)