Human Research Protection Program Departmental Policy and Procedure

6.3 Conduct of Full Board Meetings

Effective Date: September 3, 2026

I. Policy Statement

a. The UTSW IRB conducts convened meetings in accordance with applicable federal requirements for full review. 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 (IRBD) establishes the schedule for meetings. The HRPPD, Chair, or Institutional Official may direct or convene additional meetings at any time.

II. Scope

a. This policy and procedures applies to all human subject research reviewed by a convened Board.

III. Procedures for Policy Implementation

a. Meeting Preparation and Materials

i. Following the completed Human Research Protection Program Department (HRPPD) pre-review (See HRPPD Policy: 1.1. Receiving, Routing, And Administrative Review Of IRB Submissions), the HRPPD staff will document unresolved issues and notes to be forwarded to the Primary Reviewers.

ii. The HRPPD staff develops, maintains, and revises the IRB meeting schedule, as appropriate. The dates are available on the IRB website or by request.

iii. For each meeting, the HRPPD staff generates the agenda. The HRPPD

staff review the agenda for accuracy and completeness before distributing it to the IRB. The agenda serves as a guideline for the conduct of the meeting. The agenda for the meeting may include additional discussion items at the discretion of the IRB Chair, the HRPPD staff, or Institutional Official (IO).

iv. After the agenda has been completed, HRPPD staff 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 the electronic IRB system for review. IRB members are assigned studies to review, and in turn receive access to all appropriate study materials, agendas and reviewer assignments with sufficient time for their review prior to scheduled IRB meetings to be prepared to participate in deliberations and voting.

v. If special circumstances require adding a submission to the agenda, the HRPPD staff prepares a revised agenda, assigns a primary reviewer and distributes it and the applicable application information 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.

vi. All IRB members receive access to the materials necessary to review the research scheduled for the convened meeting. When research involving prisoners is reviewed, the prisoner representative is assigned as a reviewer and receives access to all materials pertaining to the research that are provided to the primary reviewer. The prisoner representative reviews the research with particular focus on the requirements of Subpart C or equivalent protections for prisoners.

b. Quorum Requirements

i. Quorum Members are those members that count towards a quorum. Quorum Members are all the IRB voting members per board. The Chair and Vice-Chair count towards a quorum and are expected to participate in the IRB votes.

ii. A quorum is defined as a majority of the quorum members present (attendance by teleconference is acceptable in order to be counted towards a quorum). Examples of how to calculate the majority of the Quorum members is as follows: e.g., If the number of Members that count towards a Quorum (Quorum Members) = 16, a Majority = 9; if Quorum Members = 15, a Majority = 8; if Quorum Members = 14, a Majority = 8)

iii. At the convened meeting, at least one member whose primary concerns are in nonscientific areas and represent the general perspective of the participants must be in attendance.

iv. When FDA-regulated research is reviewed, there must be at least one member in attendance who is a licensed physician.

v. When prisoner research is reviewed, there must be at least one prisoner representative in attendance. For DHHS-funded research involving prisoners, the IRB Chair certifies to OHRP that the duties of the IRB have been fulfilled in accordance with applicable federal requirements and as outlined in HRPP Policy 8.2 Reporting Policy and Procedure. Additionally, a majority of the Board (exclusive of member(s) representing prisoners) will have no association with any prison(s) involved in the research being reviewed, apart from their membership on the Board.

vi. When research involving individuals vulnerable to coercion or undue influence or sensitive types of research/procedures is reviewed there must be at least one knowledgeable IRB member or consultant attending the IRB Meeting.

vii. Alternate members may attend in the place of absent regular members in order to meet the quorum requirements. (See 6.1 Appointment And Evaluation Of IRB Members And Chairs)

viii. The IRB does not consider ad hoc and cultural consultants to establish a quorum.

ix. At least one un-affiliated member must attend 75% of the scheduled meetings per year. This member need not serve one role on the IRB (i.e., the unaffiliated member may also represent the general perspective of participants).

x. Members must excuse themselves from the meeting prior to discussion and during a vote when they have a conflict of interest (See 6.4 IRB Member And Consultant Conflict Of Interest). In such cases, they do not count as a part of the members necessary to constitute a vote or majority.

xi. If the quorum is lost during a meeting (e.g., loss of a majority through excused members with conflicting interests or early departure or absence of a non-scientist member, members who leave for any reason at any time do not count towards the quorum), the IRB does not take further protocol actions that require a vote unless the quorum is restored.

c. Meeting Process

i. The IRB Chair, Vice Chair, IRBD or any voting IRB member may chair the convened meeting.

ii. For review of research at a convened meeting, the IRB may request that PIs (or another knowledgeable party) attend the convened meeting when deemed appropriate.

iii. For research involving prisoners that is reviewed by the convened IRB, the prisoner representative must receive all review materials provided to

the primary reviewer and must review the research with consideration of the additional protections applicable to prisoners. The prisoner representative must participate in the convened meeting and present the review either orally or in writing for consideration by the IRB during its deliberations. These requirements apply to the initial review of the research, continuing review of the research, and any modification involving more than a minor change that requires review by the convened IRB. Continuing reviews and modifications requiring convened IRB review must be conducted using the same procedures applicable to the initial review of prisoner research. If no participants have been enrolled and the criteria for expedited review are satisfied, continuing review may be conducted using the expedited review procedure under expedited review category 8.

iv. To the extent possible, the proceedings of the meetings are confidential. Individuals such as prospective board members or representatives from non-UTSW IRBs attend as observers if approved by the HRPPD staff or Chair. The HRPPD staff obtains a statement of confidentiality from observers who have permission to attend and they excuse themselves from meetings prior to discussion and during a vote when they have a conflict of interest concerning any protocol (See 6.4 IRB Member And Consultant Conflict Of Interest). Observers do not receive a copy of application materials.

v. IRB members, consultants, observers do not participate in the review of any component of a project in which the member/person has a conflict of interest, except to provide information requested by the IRB. (See 6.4 IRB Member And Consultant Conflict Of Interest)

vi. See 2.1. Initial Review Of Research, 2.2. Continuing Review Of Research,

2.3 Modifications To Research, 9.2 UPIRSO and UADE, and 9.3 Noncompliance Review for discussion of review outcomes and controverted issues.

vii. The IRB meetings may be recorded for quality assurance purposes. The recordings will be stored securely and permanently deleted upon approval of the minutes.

viii. The HRPPD staff is responsible for preparing meeting minutes. (See 8.1 IRB Minutes)

d. Tele/Videoconference Participation

i. The IRB may conduct convened meetings by telephone or video conferencing as long as IRB members have received a copy of all of the documents under review at the meeting (as described in I.4. above), a quorum as defined above is present, and discussion occurs in real time.

ii. Such members count as part of the quorum and may vote. "Telephone polling" (where the HRPPD staff or others contact IRB members individually by telephone) does not qualify as a convened meeting. To allow for appropriate discussion, all members must be connected simultaneously for a teleconference to take place.

iii. If the member has a conflict of interest, that member may not be present during the vote or discussion (see 6.4 IRB Member And Consultant Conflict Of Interest).

e. Voting

i. IRB members may not vote by proxy (i.e., members not present at the convened meeting or not participating in the tele/videoconference call may not vote on an issue discussed during a convened meeting). However, members can provide written comments for IRB consideration.

ii. The voting may include a show of hands or voice count at the discretion of the chair.

iii. At the time of voting, the chair asks members to vote separately for each item with the following choices: for, against or abstain.

iv. Voters against or abstaining may be offered the opportunity to comment either verbally or in writing and have their comments added to the minutes.

v. Voting at a convened meeting takes place under the following conditions:

1. A quorum of the members for a specific IRB must attend (for waivers of authorization under HIPAA an additional quorum requirement includes a non-affiliated member be in attendance) for each review/action voted on at a convened meeting;
2. A passing vote must consist of a majority of members (including the Chair and Vice-Chair) in attendance voting in favor of the motion;
3. An individual who is not listed on the official IRB roster provided to the Office for Human Research Protections (OHRP) prior to the meeting may not vote with the IRB;
4. Ad hoc and cultural consultants may not participate in the vote;
5. A non-scientific member must always be in attendance for a vote;
6. A licensed physician must be in attendance to vote on FDA-regulated research;
7. If the outcome of the IRB vote is to approve pending submission of minor revisions:
    a. the IRB Chair, IRBD or designated Expedited Reviewer may review and approve the PI's response on behalf of the IRB under an

expedited review procedure, or

b. the response will be reviewed as specified by the Board during the vote if the Board determines the PI response requires review by a specific member (i.e., primary reviewer or IRB Chair) or by the Board.

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: September 2026; Author: HRPP; Description: Clarified by role who is responsible for certifying to OHPR duty fulfillment for prisoner research. Updated procedures involving prisoner research.

b. Revision date: February 2024; Author: IRB Office; Description: Meetings may be recorded for quality assurance

c. Revision date: November 2021; Author: HRPP; Description: Defined that Chair and Vice-Chair are voting members

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: August 2017; Author: HRPP; Description: New Policy

Development

f. Revision date: March 2012; Author: IRB Office; Description: IRB Written Procedures