Human Research Protection Program Departmental Policy and Procedure Manual

6.4 IRB Member and Consultant Conflict of Interest

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: January 21, 2026

I. Policy Statement

a. In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated

b. Financial Conflicts of Interest are collected annually on all UT Southwestern faculty by the Conflict of Interest Office in compliance with institutional policy. Non-UT Southwestern IRB members are required to complete the same declaration with the Conflict of Interest Office. If the Conflict of Interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or IRB Director.

c. No regular or alternate IRB member may participate in review of any research in which the member has a conflict of interest (either financial or non-financial), except to provide information as requested by the IRB Designated Reviewer or IRB Chair. Such review includes review by a convened IRB, review using expedited procedure, initial review, continuation review, review of modifications, review of unanticipated problems involving risk to participants or others, review of noncompliance with the regulations or the requirements of the IRB and any other ad hoc reviews requested by the IRB.

d. A consultant may not participate in the review or provide information to the IRB for any research project in which the consultant has a conflict of interest (either financial or non- financial). Such review includes review by a convened IRB, review using expedited procedure, initial review, continuation review, review of

modifications, review of unanticipated problems involving risk to participants or others, and review of noncompliance with the regulations or the requirements of the IRB and any other ad hoc reviews requested by the IRB.

e. Due to institutional conflict of interest, no individual from a developmental or business office may be appointed as an IRB member.

II. Scope

a. This policy and procedures applies to all IRB members and consultants to UT Southwestern

III. Procedures For Policy Implementation

a. The HRPPD staff confirms that no conflict of interest exists:

   i. When contacting an IRB Member to serve as a reviewer by querying the member at the time of assignment to review (if necessary); and

   ii. When contacting an individual to serve as a consultant by querying the individual at the time of assignment to review. Once the HRPPD staff has this confirmation, they distribute the confidentiality agreement to the consultant.

b. It is the responsibility of each voting member or alternate member of the IRB to disclose any conflict of interest when conducting a review and to excuse themselves from deliberations and voting.

c. The procedure for excusing a consultant, or IRB member, including the IRB Chair, from deliberating/voting on all full board review protocols for which there is a conflict of interest is detailed in 6.3 Conduct Of Full Board Meetings. The HRPPD staff document all conflict of interest disclosures in the IRB meeting minutes for those members who are present at meetings. The absent IRB member is not counted toward quorum and his/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes.

d. Expedited reviewers confirm that a conflict of interest does not exist prior to

making any expedited determinations for initial review, continuing review, modification review, and reportable events.

e. Consideration of Expertise for Community-Engaged Research

   i. For research involving community-engaged or community-based participatory approaches, the IRB evaluates whether review requires additional cultural, community, or population-specific expertise to adequately assess the ethical and regulatory considerations of the research.

   ii. When appropriate, the IRB may request consultation from individuals with relevant community, cultural, or subject-matter expertise, consistent with institutional policies governing the use of consultants and the management of conflicts of interest.

   iii. IRB members receive training and guidance to support the identification of research that may benefit from community or cultural consultation and to determine when additional expertise is necessary to inform the IRB's review.

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: January 2026; Author: HRPP; Description: Included process for including additional cultural, community, or population-specific expertise to

adequately assess the ethical and regulatory considerations of the research.

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

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

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