

## **Recusal Policy for IRB Members**

### **Rationale:**

Federal regulations at 45 CFR 46.107(e) prohibit a member of the IRB from participating in the initial or continuing review of any project in which the member has a “conflicting interest,” except to provide information at the Board’s request.

### **Policy:**

1. All IRB members must understand and follow UT Southwestern’s Conflict of Interest Policy located at <http://www8.utsouthwestern.edu/utsw/cda/dept41605/files/43763.html>.
  
2. Any IRB member with a conflicting interest in a project scheduled for Board review must disclose it to the IRB Coordinator or Chair and leave the room during the discussion of the project and the related vote, unless the member is merely providing information at the IRB’s request. The meeting minutes will document the recusal (i.e., the temporary absence of the IRB member during the deliberation and vote on the project with respect to which the member has a conflict). In the case of expedited IRB review (outside of a convened meeting, by a designated reviewer), the reviewer must disclose any conflicting interest in a project to the IRB Coordinator or Chair and should not review the project. If the IRB Chair is the reviewer with a conflicting interest, then disclosure should be made to the Coordinator or to the Manager of the IRB so the review can be reassigned.

### **Guidance:**

1. To whom does the IRB recusal policy apply?

It applies to all members of the UT Southwestern IRBs (including Chairs) and to ad hoc reviewers, who are not IRB members but sometimes are asked to review a project because of their expertise.

2. What is a “conflicting interest” for purposes of IRB review?

UT Southwestern defines a conflict of interest as any situation in which financial or other personal considerations may unduly influence one’s professional judgment in exercising UT Southwestern responsibilities or in the design, conduct, or reporting of research.

For purposes of this policy, a conflicting interest includes (1) participation in the project; (2) a financial interest in the project, the sponsoring company, or the technology under study; and/or (3) any other personal interest that may influence an IRB member’s judgment. A conflict may arise because of an interest of either the IRB member or his/her family member(s). A family member means a spouse, minor children, or other persons living in the same household as or financially dependent upon an IRB member.

3. Examples of conflicting interests:

“Participation in the project,” for purposes of this policy, generally means the IRB member is listed on the protocol/project, or will be included (or reasonably may be expected under academic standards to be included) as a co-author on a publication of the project’s results.

UT Southwestern defines a financial interest as anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

A “financial interest” is a “conflicting interest” under this policy if the interest is in a business that is supporting or facilitating the project, or the interest is in a business that is known to the IRB member to own (or have license rights to) the technology under study. A conflicting financial interest also shall include having an ownership interest in a patent or a patent application covering the technology that is under study.

Examples of “other personal interest” include but are not limited to:

- Serving as a Board member (of a Board of Directors or scientific advisory board) or as an executive in a business entity that is supporting or facilitating the project, or that owns or has license rights to the technology under study.
- Having other non-financial interests that may create a real or perceived conflict. These will depend on the circumstances. They may include, for example, having direct supervision over the investigator conducting the project or participating in a separate project on technology that may directly compete with the technology in the project under review.

#### 4. How and when should an IRB member disclose a potential conflicting interest?

When IRB members receive materials before a meeting, they should read the list of protocols scheduled for review and disclose any potential conflicts to the Coordinator or Chair in advance of the meeting. A designated reviewer performing expedited review of projects similarly should disclose any potential conflicts to the IRB Chair, Coordinator, or Manager of the IRBs.

Any real or perceived conflict not addressed above should be raised with the IRB Chair. If the IRB Chair determines there is even the appearance of a conflicting interest, then the member shall recuse himself or herself. The IRB Chair reserves the right to request recusal as appropriate in any particular circumstances.

In addition, every UT Southwestern faculty member must complete and submit an annual Statement of Financial Interests (“Statement”) to the Conflict of Interest (COI) Office, in accordance with the University’s Conflicts of Interest in Research policy. The COI office provides information to the IRB regarding the interests of IRB members and principal investigators to assist in the process of identifying potential conflicts.

#### 5. What other issues should be considered?

Individuals with greater responsibilities for reviewing human subjects research may have more influence over the review and approval of a project and thus should be particularly sensitive to any perceived or real conflicting interest. Accordingly, IRB Chairs and officials with research oversight authority who are involved in reviewing a project should disclose any potential conflicting interest to the Coordinator or Manager. Such disclosure may require reassignment of a protocol or additional institutional review.