

# IRB Policy 17b: IRB Member Conflict of Interest

## Revision Date: May 15, 2007, April 22, 2020

### I. Summary

Federal regulations do not permit an IRB member or consultant of the IRB to participate in the review of research in which he/she has a conflict of interest, except to provide information requested by the IRB. This requirement helps to ensure that financial or other interests do not compromise the rights and welfare of human research subjects. This policy describes when IRB members, staff, or consultants are considered to have a conflict of interest, the procedures that must be followed for disclosure, and IRB review of research when a conflict exists. Henceforth, reference to an “IRB member” in this policy refers to an appointed IRB member, consultants of the IRB, or IRB staff involved during the review of an IRB submission. This policy applies to all IRB submission review types including initial review, continuing review, review of modifications, review of unanticipated problems involving risks to participants or others, and review of non-compliance with the regulations or IRB determinations.

### II. Definitions

**Conflict of Interest:** A financial interest or other opportunity for tangible personal benefit of an individual (or his/her immediate family) to exert a substantial influence on the individual's professional judgment in exercising his/her role as an IRB member.

**Financial Conflict of Interest:** An interest of an IRB member (or his/her immediate family) of monetary value that would reasonably appear to be affected by the research under review, or an IRB member's interest in any entity whose financial interests would reasonably appear to be affected by the research. Financial interests may include, but are 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).

**Non-Financial Conflict of Interest:** An interest, other than monetary, of an IRB member (or his/her immediate family) in the design, conduct, or reporting of the research under review, or other interest that competes with an IRB member's obligation to protect the welfare of research participants and potentially compromises the objectivity and credibility of the research review process.

**Immediate Family:** For the purpose of this policy, an IRB member's spouse or domestic partner and children.

### **III. Responsibility**

At the beginning of each convened meeting, it is the responsibility of the IRB Chair to call for disclosure of conflict of interests on any agenda item. This includes, but is not limited to, initial reviews, continuing reviews, modifications, and reports of unanticipated problems. IRB members and IRB staff are responsible to declare any conflict of interest to the convened IRB before review of the protocol. Additionally, IRB members are responsible for making known any conflict of interest prior to review of any exempt or expedited protocol. IRB staff are responsible to inform Consultants of this policy, and Consultants are responsible for disclosing any conflict of interest to the IRB prior to providing any requested consultation or review recommendations.

### **IV. Disclosure and Documentation of COI**

IRB members are considered to have a conflict of interest whenever the IRB member, or their immediate family:

- 1) Has a significant financial interest as defined in Policy 17a.
- 2) Is a member of the research team designing, conducting, or reporting the research presented in the protocol.
- 3) Has a board or executive relationship related to the research, regardless of compensation.
- 4) Has responsibility for Institutional business development, such as raising funds or garnering support for research.
- 5) Has proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- 6) Is involved in research utilizing competing technology, intellectual property, or resources such that the ability to render an objective assessment is compromised.
- 7) Has any other interest of any kind that the individual believes conflicts with his or her ability to objectively review a protocol.

IRB staff must disclose any conflict of interest on any involved study, and alternate staff assignment, as appropriate, will be made by the OPHRS Director. An IRB member who declares a conflict of interest may not participate in the exempt or expedited review process of any involved study. He/she must indicate that conflict and promptly inform the IRB Coordinator for re-assignment. IRB members who realize they have a conflict of interest when first assigned an item for review at an upcoming IRB meeting must notify the IRB Chair or staff immediately so that the item can be reassigned prior to the meeting.

An IRB member who declares a conflict of interest may not participate in the review of research at a convened meeting except to provide information requested by the IRB. An IRB member who declares a conflict of interest must recuse themselves and leave the room during discussion and voting. If the IRB Chair has a conflict, he or she may not chair the meeting during the consideration of the item in which the conflict resides must leave the room during the discussion and vote. Any IRB member may recuse him/herself from review of a specific protocol for any reason, including a conflicting interest not specifically described by this policy.

IRB members who are absent from the meeting room due to conflict of interest are not counted towards quorum when the vote on the study is question is taken. The minutes will reflect that the IRB member was absent due to conflict of interest. If an alternate is present for the IRB member with the conflict, the alternate can vote and be counted toward the meeting quorum for that review item only.

References:

45 CFR 46.107

21 CFR 56.107

42 CFR 50, Subpart F

ETSU Faculty Senate Handbook

JHQVAMC HRPP SOP

VHA Directive 1200.05