



BROWN

## Institutional Review Board (IRB)

### Member and Consultant Conflict of Interest Policy

Date of Approval: June 27, 2018

---

#### I. Purpose

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 conflicting 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 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 and any consultant of the IRB.

#### 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. Policy & Procedures

**A.** Conflicts of interest must not compromise the rights and welfare of research participants or the integrity of the research review process. Federal regulations do not provide flexibility in the management of an IRB member's conflicting interest. Specifically, the regulations require that IRB members not

participate in the review of research in which they have a conflicting interest, except to provide specific information requested by the IRB.

- B.** Financial relationships with entities involved in research and the financial interests these relationships create (e.g., equity interests, payments for services, etc.) may lead to financial conflicts of interest. The financial interests that are considered conflicting interests for IRB members are the same as those for Investigators involved in research as defined in [\*Brown University Conflicts of Interest Policy for Officers of Instruction and Research\*](#). In brief, they must be related to the research protocol under review.
- C.** Conflicts of interest may also be non-financial, such as when an IRB member is asked to review research in which he/she is participating as a member of the research team. Other “personal or professional” conflicting interests may include any of the following:
- An IRB member (or member of his/her immediate family) is a member of the research team or advisory committee involved in the design, conduct, or reporting of the research
  - An IRB member (or member of his/her immediate family) is related to a member of the research team or advisory committee involved in the design, conduct, or reporting of the research
  - Other conflicting interests that appear to preclude objective assessment, at the IRB member’s or IRB Chair’s discretion. Examples may include:
    - The Principal Investigator of the research protocol is the IRB member’s immediate supervisor or the supervisor of the member’s immediate family member
    - The IRB member (or member of his/her immediate family) has an interest in competing research or is competing directly for resources such as funding or sponsorship
    - A Principal Investigator (PI) submitting a protocol may make a written request that an IRB member be excluded from review if the PI provides a written justification regarding why the IRB member has a conflict.
- D.** 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. School, Departmental or Center affiliation is not automatically considered to be a conflicting interest, except as described above.
- E.** When a conflict of interest is identified, an IRB member may not participate in any type of review of the specific research protocol conducted by the IRB with which he or she has a conflict. This includes initial or continuing reviews, review of amendments, or other reviews (e.g., adverse event reports, potential noncompliance, etc.). This requirement applies to reviews conducted by the convened IRB and those performed by expedited procedures. Any member with an identified conflict of interest at a convened meeting will be asked to leave the room during the discussion, unless asked to be present to answer questions or provide information to the IRB. He/she may not be present in the room for voting.
- F.** Office of Research Integrity (ORI) staff are responsible for documenting that an IRB member did not participate in the convened review of an IRB protocol in which the member had a conflicting interest. IRB minutes will record when the member left the room, with the reason noted as due to a “conflict of interest.” IRB members out of the room due to a conflict of interest are not counted toward the meeting quorum. ORI staff are responsible for monitoring IRB meeting attendance to ensure that quorum is maintained. If an alternate is present for the IRB member with the conflict, that person can vote and be counted toward the meeting quorum for that review item only.

## **G. Applicable Regulations**

21 CFR 54, 21 CFR 56.107; 42 CFR 50, Subpart F; 45 CFR 46.107; DHHS “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection” (05/05/04); FDA Draft Guidance “Financial Disclosure by Clinical Investigators” (02/13); NIH “Frequently Asked Questions: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (10/22/15), NSF Proposal & Award Policies & Procedures Guide (PAPPG), Chapter IX-I “Conflict of Interest Policies” (1/29/18)