

Standard Operating Procedures		
SOP #201.1 Revision 1	TITLE: IRB Member and Consultant Conflict of Interest	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

**PURPOSE**

To describe policies and procedures for identifying and managing Institutional Review Board (IRB) member and ad hoc or cultural consultant conflict of interest in any type of review (e.g. initial, continuation, amendment, noncompliance, unanticipated problem/adverse event).

**REVISIONS FROM PREVIOUS VERSION**

Updating consultant conflict of interest documentation and other administrative changes

**POLICY**

In the environment of research, openness and honesty are indicators of integrity and responsibility. These are characteristics that promote quality research and can only strengthen the research process. This policy helps ensure that personal and financial interests do not compromise the rights and welfare of human research participants. The IRB eliminates all IRB members' and consultants' conflicts of interest prior to conducting IRB reviews.

**Definitions**

A *conflict of interest* involves any situation in which an IRB member or consultant has any significant personal or financial interest in the proposed research.

*Significant personal interest* includes but is not limited to:

- An interest that the IRB member or consultant believes conflicts with their ability to objectively review a protocol including interests of the individual or immediate family member (spouse and dependent children) involved in the design, conduct, or reporting of the research protocol.

Examples of a conflicting interest are if the IRB member or consultant is any of the following:

- Principal investigator (PI) or co-investigator;
- Research team member receiving funding from the project, as listed in the budget;
- A supervisory role over the PI of the project;
- Family member of PI.

*Significant financial interest* is 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);
- A proprietary interest in the research such as a patent, trademark, copyright, or licensing agreements including royalties from such rights;
- A financial interest in the sponsor, product or service being tested;

- A position as an executive director or director of the agency or company sponsoring the research regardless of the amount of compensation;
- Any compensation that could be affected by the outcome of the research regardless of the amount of compensation.

*Significant financial interest* does NOT include:

- Salary, royalties, or other remuneration from the University;
- Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- Income from service on advisory committees or review panels for public or non-profit entities;
- An equity or financial interest that when aggregated for the IRB member or consultant and the IRB member's or consultant's spouse and dependent children meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a 5% ownership interest in any single entity;
- Salary, royalties or other payments that when aggregated for IRB member or consultant and the IRB member's or consultant's spouse and dependent children over the next 12 months are not expected to exceed \$5,000.

## **RESPONSIBILITIES**

Execution of SOP: OIRB Staff, IRB, IRB Chairs, Consultants

## **PROCEDURE**

1. Each year, OIRB staff send the Conflict of Interest Statement to all IRB members. Each IRB member completes and returns a signed statement to the OIRB.
2. No regular or alternate member may participate in review of any research project for which the member has a conflict of interest, except to provide information as requested. Such review includes initial, continuation, amendment, unanticipated problems involving risk to participants or others, and noncompliance reviews.
3. 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.
4. The procedure for excusing an IRB member, including the IRB Chair, from deliberating/voting on all full review protocols for which there is a conflict of interest is detailed in the IRB Meeting Conduct SOP. OIRB staff documents all conflict of interest disclosures in the IRB meeting minutes.
5. A consultant may not participate in the review of any research project for which the consultant has a conflict of interest. Such review includes initial, continuation, amendment, unanticipated problems involving risk to participants or others, and noncompliance reviews.
6. OIRB staff confirm that no conflict of interest exists when contacting an individual to serve as a consultant by using the Conflict of Interest Statement as well as confirming no conflict exists each time a review is conducted using the Expert Review Checklist.

## **REFERENCES**

42 CFR 50 Subpart F

OHRP May 2004 Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection