

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 05-31-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 11-06-09

OBJECTIVE

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, modification, noncompliance, unanticipated problem/adverse event, protocol violation, exemption certification)

GENERAL DESCRIPTION

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 subjects. The IRB eliminates all IRB members' and consultants' (e.g., ad hoc or cultural) 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 or clinical investigation.

Significant personal interest includes but is not limited to:

- An interest that the IRB member or consultant believes conflicts with his/her 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);
- Co-investigator;
- Study personnel receiving funding from the study, as listed in the study budget;

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- A supervisory role over the PI of the study (e.g., graduate advisor);
- 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 \$10,000 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 \$10,000.

RESPONSIBILITY

Execution of SOP: Office of Research Integrity (ORI) Staff, IRB Chair, IRB Member, Ad Hoc or Cultural Consultant

PROCEDURES

1. Each year, ORI staff send a Conflict of Interest Statement to all IRB members. Each IRB member completes and returns a signed statement to the ORI.
2. No regular or alternate member may participate in review of any research project in which the member has a conflict of interest, except to provide information as requested. Such review includes initial, continuation, exempt, modification, unanticipated problems involving risk to

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participants or others, protocol violation, and noncompliance reviews using expedited or convened procedures.

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 him or herself 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 Conduct of IRB Meetings SOP. ORI staff document all conflict of interest disclosures in the IRB meeting minutes.
5. A consultant may not participate in the review of any research project in which the consultant has a conflict of interest. Such review includes initial, continuation, exempt, modification, unanticipated problems involving risk to participants or others, protocol violation, and noncompliance reviews using expedited or convened procedures.
6. ORI staff confirm that no conflict of interest exists when contacting an individual to serve as a consultant. Once ORI staff have this confirmation, they distribute the combined confidentiality/conflict of interest agreement to the consultant. (See Conflict of Interest Statement and Confidentiality Agreement for IRB Consultant.)

REFERENCES

- 38 CFR 16.107(e)
- 21 CFR 46.103, 107
- 21 CFR 56.107
- 21 CFR 54 (as reference)
- 42 CFR 50 Subpart F
- OHRP May 2004 Financial Relationships and Interests in Research Involving Human Subjects:
Guidance for Human Subject Protection