IRB Member, Ad Hoc Consultant, and OPRS Staff Conflicting Interest Policy

Version: 1.7; Date: 05/22/2017
Approved by: Human Protections Administrator, Director of OPRS, and Executive IRB Chair
AAHRPP REF #: 181
AAHRPP Elements: II.1.C., II.1.D.

DEFINITIONS:

I. FAMILY: means spouse or domestic partner, parents, siblings, and children.

II. FINANCIAL INTEREST RELATED TO THE RESEARCH: means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

POLICY:

I. Persons who are responsible for business development are not permitted to serve on the IRB, be an ex-officio IRB member, or to be involved in the day-to-day operations of the IRB. As indicated in the IRB Member Recruitment and Appointment SOP, all potential recruits are screened to ensure that they do not have a competing business interest.

II. An IRB member with a conflicting interest will not be counted towards quorum.

III. An IRB member, consultant, or OPRS staff member is automatically considered to have a conflicting interest when the member/consultant or the member's or ad hoc consultant's family has any involvement in the design, conduct, or reporting of the research or a significant financial interest (SFI) related to the research that meets the following thresholds:

A. Remuneration received from an external entity at present or in the 12 months preceding the disclosure that when aggregated for the individual and family members the value totals or exceeds $5,000. The $5,000 threshold also applies to salary, royalties, and other payments aggregated for the individual and family members.

B. Ownership in a publicly-traded equity (plus any remuneration) when the value meets or exceeds $5,000.

C. Any level of ownership in a privately-held equity regardless of the dollar value.

D. Intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, and royalties from such rights).

E. Any other relationships that might present a conflict of interest, such as fiduciary interests (paid or unpaid positions as director, officer, or other management role in a for-profit or not-for-profit entity sponsoring or related to the research) or
interests in which compensation or the value of equity or property rights or the combination of interests might affect the outcome of the research.

F. Any gift regardless of value from a company or other entity that has an interest in the outcome of the human subjects research under review.

The following SFIs are exempt (42 CFR 50.603) from the disclosure requirements:

i. salary, royalties or other remunerations paid by the University of Illinois; including intellectual property rights assigned to the University of Illinois and agreements to share royalties related to such rights;

ii. income from investment vehicles (mutual funds or retirement account that are not managed directly by the individual);

iii. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a); an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

iv. income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a). (e.g., NIH review panel)

IV. “Other Interest” includes but is not limited to:

A. Listed member of the research team;

B. Supervision of a project (i.e., an IRB member is the investigator’s Faculty Sponsor, or a situation exists in which any investigator must report to or is under the professional supervision of the IRB member);

C. Personal relationship with investigator (IRB member has a family relationship or other close personal relationship with the investigator);

D. Other personal interests that may be conflicting interests, such as if (a) the IRB member has an interest that he/she believes conflicts with the member’s ability to review a project objectively; or (b) the IRB member is in direct competition with the investigator for limited resources, funding, sponsorship, or research subjects, (c) the IRB member is considered a personal or professional adversary of the investigators, or (d) the IRB member is a subordinate to the investigator. For (b), (c), and (d), the IRB member should disclose the circumstances to the IRB Chair or OPRS Director for a determination of whether a conflicting interest exists; and/or

E. Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

PROCEDURES:

I. IRB Member Conflict of Interest.

A. IRB members with a conflicting interest must absent themselves from the meeting room for the review of research including the discussion and voting except to provide information requested by the IRB. IRB members are responsible for the self-identification of their conflicting interests in advance of
convened IRB review, review using the expedited procedure, review of unanticipated problems involving risk to participants or others, and review of non-compliance.

B. When an IRB member has a conflicting interest at a meeting the Chair will ask the remaining IRB members whether they have any questions regarding the conflict of interest for the IRB member with a conflicting interest. Then the IRB Chair will ask the IRB member with a conflicting interest to leave the room until the discussion and voting is complete.

II. Ad Hoc Consultant Conflict of Interest.
   A. When the IRB uses an ad hoc consultant to aid in the review of a particular research protocol, the consultant must not have a real or perceived conflict of interest with the research. When an ad hoc consultant is identified, OPRS staff informs them of this policy and determines whether the consultant has a conflicting interest. Ad hoc consultants with a conflicting interest may not serve as a consultant.

III. OPRS Staff Conflict of Interest.
   A. OPRS staff are expected to self-identify when they have a conflicting interest with a protocol and to not be involved in any protocol in which they have a conflicting interest.

IV. Conflict of Interest Declaration for IRB Members, Ad Hoc Consultants, and OPRS Staff
   A. IRB members complete the COI Declaration at the time of appointment and re-appointment.
   B. Ad hoc consultants are asked to complete the COI Declaration at the time of being approached for their services.
   C. OPRS Staff complete the COI Declaration at the time of hiring and at the time of appointment/re-appointment if the staff is also an IRB member.
   D. The COI Declarations are reviewed by OPRS staff. If a COI is disclosed, the staff will discuss the COI with the OPRS Director, Chair, and Assistant Director, if applicable.
   E. The COI Declarations are scanned and saved on the OPRS shared drive. The hard copies are stored in OPRS.

V. Research reviewed by CHAIRb
   A. The above policies and procedures also apply to research reviewed by CHAIRb.

REFERENCES:

Public Health Service 42 CFR 50 Subpart F and 45 CFR Part 94 revised August 2011
21 CFR 56.107(e)
38 CFR 16.107(e)
45 CFR 46.107(e)
REVISION LOG:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1, 10/01/08</td>
<td>1.0, 04/18/07</td>
<td>Reformatted to fit new policy template.</td>
</tr>
<tr>
<td>1.2, 8/12/09</td>
<td>1.1, 10/01/08</td>
<td>Included a statement that IRB members with a conflicting interest will not be counted towards quorum.</td>
</tr>
<tr>
<td>1.3, 5/25/12</td>
<td>1.2, 8/12/09</td>
<td>Updated thresholds for financial disclosures, definition of family, exemptions, and references.</td>
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<tr>
<td>1.4, 7/24/15</td>
<td>1.3, 5/25/12</td>
<td>Updates to logo and OPRS website address.</td>
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<tr>
<td>1.5, 2/20/16</td>
<td>1.4, 7/24/15</td>
<td>Addition of CHAIRb; revision to include the process for completing, reviewing, and storing COI disclosure forms.</td>
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<tr>
<td>1.6, 10/24/16</td>
<td>1.5, 2/20/16</td>
<td>Clarification regarding “Other Interests”.</td>
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<tr>
<td>1.7, 5/22/17</td>
<td>1.6, 10/24/16</td>
<td>Inclusion of the stipulation regarding persons responsible for business development.</td>
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