MANAGING CONFLICTS OF INTEREST OF IRB MEMBERS AND CONSULTANTS

DESCRIPTION

The University of Cincinnati (UC) Institutional Review Board (IRB) must review and manage any significant financial and ethical conflict of interest (COI) disclosed by IRB members and consultants.

RESPONSIBILITY

The IRB is responsible for reviewing and managing all conflicts of interest which have been disclosed by its members and consultants for all types of review. Duties related to assuring compliance may be delegated to designees.

DEFINITIONS

Financial interest related to research: A monetary interest related to the sponsor, product or service being tested. May include anything of monetary value, including, but not limited to salary, consulting fees, honoraria, equity interests, interests in real or personal property, dividends, royalties, rent, capital gains, and/or intellectual property related to the sponsor, product or service being tested

Non-Financial Interest related to research: A nonmonetary interest related to the sponsor, product or service being tested that competes with the IRB member’s or consultant’s obligations and objectivity. Examples may include the following: a) direct competition with the investigator for research subjects, funding, sponsorship; b) when the researcher is related to the IRB member (i.e., spouse or child) or whether the IRB member has authority over the researcher (i.e., supervisor, thesis advisor).

Immediate Family:
“Family” includes spouse, domestic partner and dependent children

PROCESS

No IRB member or consultant may participate in the IRB’s initial or continuing review of any human research project in which the member or consultant has a real or potential COI, except to provide information requested by the IRB.
Managing Conflicts of Interest of IRB Members and Consultants

A COI requires disclosure when an individual is or may be in a position to influence the decisions of the IRB in ways that could lead to any form of personal gain for the individual or his/her family, or which might prevent the IRB member or consultant from impartially reviewing a research project. A COI is considered to be present when an IRB member or consultant or their immediate family member meets one or more of the following criteria.

- Owns equity or other financial interest in the sponsor or the company whose drug, procedure, device or software is being tested
- Holds intellectual property rights patent(s), trademark(s), copyright(s) or other interest(s), the value of which may be influenced by the outcome of the research
- Holds a position of senior management, officer or director of the sponsor or the company whose drug, procedure, technique, device or software is being tested
- Is a scientific advisor or consultant to the sponsor or company
- Receives income from the sponsor or company
- Is involved or is likely to become involved in the design, conduct, or reporting of the research
- Has any other financial interest that may appear to conflict with the protection of participants
- Has any other interest that the member believes may appear to conflict with the protection of participants

Any IRB member or consultant who has a COI must take the following action.

- Provide a description or clarification of the COI before contributing to the review process, or as requested by the IRB
- Participate in the review process only as determined by the IRB on a case-by-case basis depending on level of COI, and only to the extent of providing information requested by the IRB
- Leave the convened meeting prior to final discussion and vote on the item under review

The IRB Chair or designee shall provide this policy to a consultant when the services of the consultant are engaged so the consultant may provide a description or clarification of any COI. If a COI exists, the IRB Chair will provide a description to the IRB so the Board may determine either that the COI will not prevent the consultant from providing the requested service or that another consultant with expertise but without a COI must be engaged. IRB members and consultants with a conflict of interest are not counted towards quorum.

Human Research Protection Program (HRPP) staff will record in the minutes of the IRB meeting the name of any Board member who was absent due to COI.
Applicable Regulations and Documents:
45 CFR 46.107
21 CFR 56.107
Policy I.01 *Composition of the IRB*
DHHS Revised COI Rule (Federal Register Vol. 76, No. 165, pp 53256-53293, dated 8-25-2011, effective 9-26-2011)

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<th>Revised By: D. Oneill</th>
<th>Revised By: C. Norman</th>
<th>Revised By: J. Strasser</th>
<th>Revised By: A. Braggs-Brown</th>
<th>Revised By: J. Strasser</th>
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<td>07/2007</td>
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<td>IRB Program Manager has been changed to IRB office staff according to currently used terminology</td>
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<td>08/2012</td>
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<td>Format and wording revisions to be consistent with other HRPP Procedures.</td>
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Date Adopted March 2015 Signature signed copy on file