

Institutional Review Board Policies and Procedures Manual

SECTION 4: CONFLICT OF INTEREST

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4.1 CONFLICTS OF INTEREST (COI) FOR SPONSORED PROGRAMS

A potential *conflict of interest* (COI) exists when an individual's personal or private interests might lead an independent observer reasonably to question whether the individual's professional actions or decisions are determined by considerations of significant personal interest, financial or otherwise. In accordance with federal regulations, the Institution has a responsibility to manage, reduce, or eliminate any actual or potential COI that may be presented by a significant financial interest or relationship.

Per the Institution's [Financial Conflicts of Interest in Research and Sponsored Programs Policy](#), all investigators and persons responsible for the design, conduct or reporting of research or sponsored programs are required to complete an annual survey to disclose any significant financial interests or relationships, and update it within 30 days of any new significant financial interest or relationship.

The Chief Operating Officer of the Research Institute and the Chief Compliance and Integrity Officer or their designee(s) review all significant financial interest disclosed. A plan to reduce, manager, or eliminate the conflict of interest is developed and implemented when the significant financial interest or relationship has the potential to affect the design, conduct, or reporting of research activities. The IRB is given the opportunity to review the plan as it relates to any study involving human subjects and has the final authority to decide whether to approve a protocol given the circumstances of the COI and the management plan. The management plan will be reviewed, amended if necessary, and approved by 1) the convened IRB for any research initially reviewed by the full board, or 2) the IRB Chair for any research meeting the criteria for expedited review.

4.2 CONFLICT OF INTEREST FOR IRB MEMBERS

A. Ethical Context and Principles

The Institution is committed to ensuring the IRB is composed of impartial members who are not subject to undue influence by pressures to approve research in which the IRB member (or an immediate family member) has a COI. It is essential that potential COIs are identified and disclosed to preserve the integrity and ethical propriety of research conducted and to maintain public trust in and support for the Institution's research endeavors. The Institution's commitment to the integrity and ethical conduct of research may be compromised if the self-interest of an IRB member interferes with, or is perceived to interfere with, professional judgment.

A COI exists when an IRB member or an immediate family member (spouse, dependent children, and other persons living in the same household) has any financial or personal/professional interest or relationship that could or give the appearance of directly and significantly affecting the IRB member's ability to be objective and to exercise independent judgment in protecting the rights and welfare of human research participants. All IRB members must identify and disclose a potential conflict of interest to the IRB chair. Where a COI exists, the IRB member may not participate in the discussion/review of any study submission, except to answer any questions from the IRB prior to leaving the room for the IRB deliberations and vote.

Per 45 CFR 46.107(e) and 21 CFR 56.107(e), all IRB members must notify the IRB Chair or Vice-Chair of a potential COI in advance of the IRB meeting, or if assigned as a primary,

secondary or expedited reviewer. Prior to the beginning of each meeting, IRB members will be asked to declare any potential COI related to the protocols under review. The IRB member need not explain in detail the nature of the potential conflict but must provide sufficient detail for the IRB Chair to determine whether the disclosed potential COI requires the IRB member to leave the room during voting and to take the other actions set forth below. If the IRB member chooses not to describe the potential conflict in such detail, the potential conflict may be deemed an actual COI and the steps discussed below shall be followed.

B. Financial, Personal and Professional Relationships That May Create Conflicts of Interest

Guidance for determining if there is a significant financial interest that must be disclosed may be found in the [Financial Conflicts of Interest in Research and Sponsored Programs Policy](#).

Likewise, other professional or personal interests that could be pose a COI should be disclosed such as the following:

The IRB member or an immediate family member:

- i. serves as an investigator or as a scientific/medical advisor for the study/PI/sponsor;
- ii. is an advisor or direct supervisor of a trainee's (e.g., medical, graduate or undergraduate student) research. Please note that a department chair position alone may not be sufficient to create a "direct, supervisor" relationship;
- iii. holds a position as director, officer, partner, trustee, or any other significant/decision-making position in the company sponsoring the research; or
- iv. has a personal relationship, or a conflict, with any investigator(s) listed on the IRB application for review that would potentially cause the IRB member to be perceived as less than objective in his/her review.

If an IRB member is uncertain if a potential COI exists, they are encouraged to consult with the IRB Chair/Vice-Chair.

C. Determination that a COI Exists

After disclosure to the IRB Chair of a potential COI described above, the IRB Chair or Vice Chair will determine whether an actual COI exists.

D. Action by the IRB

An IRB member must be recused from the discussion and vote on the study submission in which a potential COI exists. The IRB meeting minutes will reflect such recusals.