

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,