

The Christ Hospital IRB

Section: 10

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IRB REFERENCE MANUAL SECTION 10 CONFLICTS OF INTEREST

10.0 CONFLICTS OF INTEREST

Conflicts of interest and commitment in research can adversely impact the integrity of research results and the confidence of prospective volunteers in the research enterprise. Researchers are often faced with competing demands on time, effort and responsibilities. A conflict of interests occurs when a researcher must contend with two or more competing concerns, such as achieving publication, retaining outside funding or honestly reporting research results. A conflict of commitments occurs when a researcher engages in competing obligations, such as collaboration on another project, preparing a new grant application, teaching or peer review. (Ref. [APA Conflicts of Interests and Commitments](#))

The Christ Hospital (TCH) Institutional Review Board (IRB) seeks to avoid these negative repercussions by identifying, disclosing, and avoiding or managing such conflicts.

The Christ Hospital has bylaws, policies, procedures and practices concerning staff members' outside financial or management interests which could form the basis of a conflict, and seeks to protect at least the following values:

- a. Objectivity and integrity in research
- b. Open publication of research results
- c. Appropriate use of sponsor or hospital funds
- d. Maintenance of appropriate relationships with and fulfillment of obligations to colleagues
- e. Fulfillment of administrative duties
- f. Integrity of academic decision making
- g. Avoidance of "pipelining" institutional intellectual property to an outside entity
- h. Protection of and appropriate informed consent with human subjects

10.1 Identification of Conflicts of Interest of Investigators and Research Staff

10.1.1 IRB Identified

At the time of initial submission and continuing review of research, a Financial Conflict of Interest (FCOI) disclosure must be completed by

all investigators and other key research personnel involved in the study. This provides an opportunity for investigators to certify that neither they, nor their immediately families*, have any significant financial interest in the proposed research. When an investigator, or any other key personnel, on a proposed research project discloses that they (or their spouse or dependent children) have significant financial or management interests in a sponsored project, further review by the IRB is required to determine what, if any, management plan is necessary to minimize the risk of imparting bias into the research. (Ref. SOP 2.13 Investigator Disclosure of Financial Interest)

10.1.2 Institution Identified

In compliance with The Christ Hospital conflict of interest policies, the Institutional Official may also receive certain disclosures of outside activities generated including disclosure of significant financial interest. The Institutional Official reviews the disclosures and will report any conflict of interest to the IRB Chair and appropriate administrative committee.

10.2 Conflicts of Interest of IRB Members and Consultants

IRB members and consultants will not participate in any IRB action taken including the initial and continuing review of projects in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. Consultants with a conflicting interest are required to disclose their conflicting interests to IRB members reviewing the research, are excluded from discussion (except to provide information requested by the IRB), and must leave the meeting room during convened IRB meetings when discussion and voting take place.

An IRB member is considered to have a conflicting interest when the IRB member or an immediate family member* of the IRB member:

- a. Is the project director or other member of the research team who has a financial interest in the research which has a value that cannot be readily determined, or a value that may be affected by the outcome of the research
- b. Has a financial interest in the research with value exceeding the specified monetary threshold in The Christ Hospital Conflict of Interest policy
- c. Has received or will receive any compensation which has a value that may be affected by the outcome of the study
- d. Has a proprietary interest in the research: property or other

- financial interest in the research including, but not limited to, a patent, trademark, copyright or licensing agreement
- e. Has received payments from the sponsor that exceed the specified monetary threshold in The Christ Hospital Conflict of Interest policy
 - f. Is an executive or director of the agency/company sponsoring the research
 - g. In any other situation believes that an interest conflicts with his/her ability to deliberate objectively on a research protocol

Except when requested by the IRB to be present to provide information, IRB members with a conflict of interest will be absent from the convened meeting room while the IRB reviews the research associated with the member holding the conflict of interest. The IRB chair will allow board discussion only after the conflicted member has recused him/herself. The absent member is not counted toward quorum. His/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes.

10.3 Institutional Conflicts of Interest

10.3.1 Equities in Outside Organizations

When conducting reviews of research projects, the Institutional Official for Research receives and reviews information on any Hospital equity in an outside organization associated with the research and seeks to manage any conflict-of-interest risk associated with that equity including any significant financial or management interest in the outside entity by hospital administrators and manages those conflict in light of the special need for protections from research risks. In addition, the Hospital's equity in start-up companies is managed as part of the Institution's broader investment portfolio and therefore no different from other institutional investments. This helps avoid bias or favoritism. The Chief Financial Officer, not the Institutional Official for Research, coordinates hospital investments utilizing outside managers to assist with investment strategy. Thus, a determination to liquidate the Hospital's investment in a holding is never a research decision.

10.3.2 Gifts

Organizational financial conflicts of interest involving gifts are evaluated for potential institutional COIs when the donor has an interest in the research. Ref. The Christ Hospital Policy 4.21.116 Conflict of Interest - Managers and Employed/Contracted Medical Staff Members; The Christ Hospital Policy 4.21.124 Conflict of Interest – Board of Directors

10.4 Management Plans

The convened IRB reviews any disclosures of significant financial interest upon receipt and at the time of initial and continuing review. The IRB develops and

approves plans to manage the interest, as appropriate, to minimize the risk of imparting bias into the research. Management plans are typically tailored to the specific study and/or sponsor and the researcher's financial interests. Examples of special protections used in management strategies may include, but are not limited to:

- a. Disclosing the potential COI to the subjects in the informed consent form
- b. Reducing the researcher's role in the research (less interaction with subjects, less data analysis)
- c. Adding an independent monitor to the study team to make sure that the research procedures are transparent
- d. Precluding the conflicted research from obtaining informed consent from subjects
- e. Blinding the conflicted research to treatment arm(s)
- f. Requiring researchers to disclose their financial interest in presentations and publications related to the research

Ref. SOP 2.13 Investigator Disclosure of Financial Interest; TCH Policy
1.05.104 Human Research Protections Program Conflict of Interest

* Immediate family is defined as a spouse, dependents or members of one's household.