

**The Christ Hospital IRB**

**Section:** 10

**Effective Date:** 07/02/07

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**AAHRPP Element:** I.6.A, I.6.B, II.1.D, III.1.B

**IRB REFERENCE MANUAL  
SECTION 10  
CONFLICTS OF INTEREST**

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**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. The Christ Hospital IRB seeks to identify, disclose and avoid or manage conflicts to avoid these negative repercussions.

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

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

**10.1 Conflicts of Interest of Investigators and Research Staff**

Identification of Conflicts

IRB Identified: Every proposal for research requires an internal document called the "Disclosure of Financial Interest" be completed by all researchers involved in the study. This form requires certain certifications and disclosures, and provides an opportunity for the investigators to provide certifications he/she, nor his or her immediately family\*, has a significant financial interest in the proposed research. When an investigator on a proposed research project, or any key personnel, indicate on the form that they (or their spouse or dependent children) have significant financial or management interests in a sponsored project,

formal disclosures are required. (See SOP 2.13 “Investigator Disclosure of Financial Interest”.)

Institution Identified: The Institutional Official may also receive certain disclosures of outside activities generated in compliance with The Christ Hospital conflict of interest policies, including significant financial interest disclosed. 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**

IRB members and consultants will not participate in any IRB action taken, including the initial and continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Consultants with a conflicting interest are excluded from discussion except to provide information requested by the IRB, leave the meeting room for discussion and voting, and disclose their conflicting interests to IRB members reviewing the research. IRB members are expected to self-identify conflicting interests.

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

1. is the project director, or other member of the research team.
2. has a financial interest in the research whose value cannot be readily determined or whose value may be affected by the outcome of the research.
3. has a financial interest in the research with value that exceeds the specified monetary threshold in The Christ Hospital Conflict of Interest Policy.
4. has received or will receive any compensation whose value may be affected by the outcome of the study.
5. 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).
6. has received payments from the sponsor that exceed the specified monetary threshold in The Christ Hospital Conflict of Interest policy.
7. is an executive or director of the agency/company sponsoring the research.
8. any other situation where an IRB member believes that another interest conflicts with his/her ability to deliberate objectively on a protocol.

Except when requested by the IRB to be present to provide information, IRB members will be absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest. The Chair

will allow for board discussion once the conflicted member has recused him/herself. The absent member is not counted toward quorum and 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**

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. Furthermore, he/she receives information on any significant financial or management interest in the outside entity by Hospital administrators and manages the 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, and 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.

\*Immediate family is defined as spouse, dependents or members of his/her household.