The Christ Hospital IRB
Submitted By: Erica Jones
Reviewed By: Steve Roberts, MD
Approved By: Steve Roberts, MD
(II.I.D, II.2.A, III.1.B)

Number: 2.13
Effective Date: 03/27/09
Revised/Reviewed Date: 09/22

STANDARD OPERATING PROCEDURE

Investigator Disclosure of Financial Interest

POLICY:

Each funded and/or FDA-regulated research project submitted to the IRB for review must be accompanied by a Disclosure of Financial Interest Statement for each principal investigator, sub-investigator, and all key research personnel directly involved in research activities and/or interacting with research subjects.

OVERVIEW:

Public trust in the research enterprise and the legitimacy of its powerful role in society require a constant amenability to public scrutiny. Consequently, it is necessary at all times to assure the continued confidence of the public in the judgment of scholars and clinicians and in the dedication of academic research institutions to the integrity of the research enterprise. The strength of this assurance is based on the assumption that scholars are honest and conduct their research with the highest standards and integrity.

This policy is intended to serve subjects of human research. This policy is not intended to eliminate all situations of conflict of interest, but rather to enable individuals to recognize situations that may be subject to question and resolve them so as to avoid conflicts of interest. Thus, an integral part of the policy is disclosure whereby individuals regularly review their professional activities.

Individuals directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied. A conflict of interest arises when a researcher is or may be in a position to put his or her own interest before the best interests of research subjects. Conflicts involving the IRB itself or conflicts involving the institution must be managed. In order to manage such conflicts, the IRB must be informed of potential conflicts of interest. Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict with the best interest of the subject in order for the research to be considered for approval.

I. Federal Regulations and Policies Governing Disclosure of Individual COI

a. PHS-funded research
Pursuant to PHS regulation at 42 CFR 50, each researcher responsible for the design, conduct or reporting of research funded by the PHS must disclose any significant financial interest (SFI). SFI is defined as a financial interest consisting of one or

more of the following interests that reasonably appears to be related to the researcher's organizational responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. (For purposes of this definition, remuneration includes salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other measures of fair market value);
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators must also disclose any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state of local government agency, an institution of higher education as defined at 20 U.S.C.1001(a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

b. <u>FDA-regulated research</u>
FDA regulation requires applicants submitting marketing applications for drugs, biologics, or devices to certify the absence for certain financial interests or to disclose financial interests of researchers who conduct clinical studies covered by the regulation at 21 CFR 54.4(a). The FDA may refuse to file any marketing application that does not contain a disclosure of financial interests or a certification that the applicant acted with due diligence to obtain researchers' disclosures, but was unable to do so.

II. TCH IRB Required Disclosure

All investigators and key research personnel directly involved in research activities and/or interacting with research subjects must submit a disclosure as to whether any of the financial interests/arrangements listed below apply to themselves or to an individual in their immediate family (such as spouse, dependent children, or members of their household) in relation to the study. The reporting period is the 12 months preceding the date of their disclosure.

1. Having been an executive, director, or employee of the sponsor of this study.
2. Having received remuneration from a sponsor/funding agency when the aggregated value received during the 12-month period preceding the disclosure exceeds $5,000.
3. Having received reimbursed or sponsored travel that is related to investigator's responsibilities for this study.

4. Having equity interests (e.g. stocks, stock options, or other ownership interests) of any value for a non-publicly traded company or that exceeds $5,000 for a publicly traded company during the 12 month period preceding the disclosure.
5. Having income related to intellectual property rights and interests (e.g. patents, trademarks, service marks, and copyrights).
6. Having agreed to or plan to accept recruitment bonuses for enrolling subjects into the research.
7. Receiving any significant payments of other sorts not aforementioned including monetary values more than $5,000. These may be in forms such as a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation, or honoraria.

III. Management Plans

The convened IRB review reviews any disclosures of significant financial interest upon receipt of a 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 plans may include, but are not limited to-

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

IV. Education

Education is required of each individual initially and at least every three years. The education will be done through a CITI course module when the researcher is up for renewal, which is every three years.

Education is required immediately when financial conflict of interest policies are revised in a manner that changes researcher requirements, a researcher is new to the organization, or a researcher is non-compliant with financial conflict of interest policies and procedures.

REFERENCE:

45 CFR 46.109(b), 21 CFR 54.4(a-d)(f); 21 CFR 54; 21 CFR 56.109(b); 42 CFR 50, Subpart F

PROCEDURE

I. Disclosure

Investigators and key research personnel are responsible for completing a Financial Conflict of Interest disclosure at the time of initial submission of a new research project.

Investigators and key research personnel are required to disclose any new financial interest relevant to the research within 30 days after they become aware and they must also report at the time of continuing review if any conflict has developed since last review.

PHS-funded research only- All sponsored travel must be reported, either in advance of it happening or within 30 days thereafter, for PHS funded research. Researchers and staff must submit a letter explaining any travel reimbursement or sponsored travel of the researchers and research staff related to institutional responsibilities. (at a minimum travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.).

II. Review

The IRB Staff ensures that disclosure forms are included in the submission documents and completed appropriately for IRB Chair's initial review. The IRB Chair conducts an initial review of all IRB applications and accompanying disclosures. When a significant financial interest is disclosed, the Chair sends to the convened IRB for review. The matter may be presented to the hospital Ethics Committee if deemed appropriate. The convened IRB evaluates and determines an appropriate management plan, if any, prior to research approval. The Institutional Official is notified of any management plan.