STANDARD OPERATING PROCEDURE

Investigator Disclosure of Financial Interest

POLICY:

Each protocol submitted to the IRB for review must be accompanied by a Disclosure of Financial Interest Statement for each clinical investigator, co-investigator and all research staff who are directly involved in the treatment or evaluation of research subjects in the study.

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.

When following DHHS regulations, significant financial interest means:

A financial interest consisting of one or more of the following interests of the Researcher (and those of the Researcher’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional 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 the occurrence of 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.

• 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:
  o Financial conflict of interest policies are revised in a manner that changes researcher requirements
  o A researcher is new to the organization
  o A researcher is non-compliant with financial conflict of interest policies and procedures.

Updated COI information will be available on The Christ Hospital website and an electronic letter will be sent to all department directors and research staff relaying the new information when it is updated.

REFERENCE:
21 CFR 54.2(a-d)(f); 21 CFR 54; 42 CFR 50, Subpart F

PROCEDURE

INVESTIGATORS AND RESEARCH STAFF:

  o Must submit a completed Christ Hospital IRB Disclosure of Financial Interest form to the IRB when submitting documents for approval of a new study. NOTE: In lieu of
completing the IRB Disclosure form, Investigators may choose to submit a copy of their completed/signed Financial Disclosure Form required by the sponsors if under $5,000.
  o Must submit a letter explaining 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.). **ONLY if you receive any Public Health Services (PHS) grants, including NIH, CDC, HRSA, etc. in other words, during any times that you have PHS funding, you must report all sponsored travel, either in advance of its happening, or within 30 days thereafter**
  o Discloses conflict(s) of interest in the informed consent if requested by the IRB.
  o Must submit a new Disclosure form at time of continuing review if any conflict has developed since the last time the study was reviewed.
  o If you meet any of the criteria listed below under the examples of reportable and non-reportable activities, you must describe the financial interest and any steps planned to prevent the financial interest from interfering with the design, conduct, or reporting of the research including interfering with the protection of participants.

**IRB STAFF:**

  o Assures that Disclosure forms are included in the submission packet and completed appropriately for IRB Chair’s review.
  o Sends letters to investigator(s) as requested by the IRB Chair if conflict(s) requires disclosure in the informed consent document, or if conflicts must be resolved prior to IRB review.
  o Keeps copies of all correspondence with the protocol submission materials.

**IRB CHAIR:**

  o Based on information provided by the researcher for review, may determine that:
    1. No conflict exists.
    2. A conflict exists and must be disclosed to the subjects in the informed consent document, and drafts a letter to the investigator informing of the need to revise the consent form before submitting to the full IRB.
    3. A conflict exists and the researcher must resolve the conflict before the research can be approved;
       ▪ Drafts letter to investigator informing him/her that the IRB will not review the protocol for approval until or unless the conflict has been resolved, noting that the matter is being addressed by the Institutional Official.
       ▪ Refers the matter to the Institutional Official for resolution.
       ▪ May present case to the hospital’s Ethics Committee if felt by the IO and IRB Chair to be appropriate.
    4. Informs the convened IRB of the evaluation and any management plan
    5. The convened IRB has the final authority to decide whether the interest and management, if any, allowed the research to be approved.

**EXAMPLES OF REPORTABLE AND NON-REPORTABLE ACTIVITIES:**

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Non-Reportable Activities: The following activities and relationships do not need to be reported and do not represent a conflict of interest because they have been generally accepted practices and do not violate fundamental ethical principles:

1. Receiving royalties for published scholarly works and other writings.
2. Accepting honoraria for commissioned papers and occasional lectures.
3. Receiving payment for reasonable travel and lodging expenses related to presentations of scholarly work or to a person’s academic endeavor.
4. Investing in mutual funds.
5. Participating in a hospital approved practice corporation.
6. Payments for clinical research to an approved practice corporation or to a department fund for salary or other expenses of conducting clinical trials.

Reportable Activities: The employee or immediate family (spouse, dependents or members of his/her household):

1. Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
   - Does not exceed $5,000 when aggregated for the immediate family.
   - Publicly traded on a stock exchange.
   - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
   - Does not exceed 5% interest in any one single entity when aggregated for the immediate family.

2. Compensation related to the research unless it meets two tests:
   - Does not exceed $5,000 in the past year when aggregated for the immediate family.
   - No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.

3. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

REVISION HISTORY:

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<th>Date Revised</th>
<th>Reason For Change</th>
<th>Revised By</th>
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<td>Revised amount of Ownership interest, stock to $10,000</td>
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<td>8/29/12</td>
<td>Revised Investigator Section</td>
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<td>04/05/13</td>
<td>Updated education timeline and research staff</td>
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