

The Christ Hospital IRB

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STANDARD OPERATING PROCEDURE

Review of Financial Conflicts of Interest

1.0 PURPOSE

- 1.1** This procedure establishes the process to evaluate a financial disclosure of an investigator or other key research personnel directly involved with the design, conduct, and reporting of research (“Covered Person”) that could result in a financial conflict of interest.
- 1.2** The process begins when the Conflict of Interest (COI) Officer determines that a Covered Person has reported a financial disclosure may relate to the human research.
- 1.3** The process ends when the COI Officer has evaluated the disclosed financial relationship, reviewed it with the IRB COI Committee and communicated the results of this evaluation to the IRB; and the IRB has issued a final determination.

2.0 SCOPE

- 2.1** This policy pertains to all investigators and other key research personnel directly involved in research activities and/or interacting with research subjects on any federally funded and/or FDA-regulated research project at The Christ Hospital.

3.0 POLICY

- 3.1** The Institutional Review Board (IRB) Chairman serves as the COI Officer.
- 3.2** The Christ Hospital Institutional Review Board (IRB) serves as the Conflict of Interest (COI) Committee for all applicable research studies engaged in at The Christ Hospital.
- 3.3** For any or all steps of this procedure, the COI Officer may have the IRB COI Committee review a financial disclosure when the COI Officer believes that a significant financial interest may result in a financial conflict of interest related to the research.
- 3.4** At any time, the COI Officer or IRB COI Committee may consult TCH General Counsel or the hospital Ethics Committee, if appropriate.
- 3.5** Covered Persons must complete an annual disclosure to the institution per institutional rules and state and federal policies. Individuals must update their disclosure within 30 days of acquisition or discovery of a new outside activity.
- 3.6** Covered persons are required to complete FCOI training at least every three years, and immediately when:
 - 3.6.1** Joining the organization.

- 3.6.2 Financial conflicts policies are revised in a manner that changes investigator requirements.
- 3.6.3 Non-compliance with conflict-of-interest policies and procedures.
- 3.7 Covered Persons are required to disclose all paid and unpaid outside interests per institutional rules. The COI Officer determines if a financial interest is related to or appears to be related to the research. Disclosure of financial interests occur annually and within 30 days of discovering or acquiring a new outside interest.
- 3.8 The COI Officer and/or IRB COI Committee, as applicable, reviews the disclosure of financial interest of a Covered Person at the following times:
 - 3.8.1 During initial review, when being added as key research personnel on a new protocol submission.
 - 3.8.2 When being added as key research personnel to an existing research study.
 - 3.8.3 At least annually on submission of continuing review.
 - 3.8.4 Within 30 days of discovering or acquiring a new outside interest.
- 3.9 Covered Persons who are planning to participate in research must disclose their reimbursed or sponsored travel related to their institutional responsibilities no later than at the time of application for research. These individuals must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence. Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. Travel that is reimbursed or sponsored by the following are not required to be disclosed: a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- 3.10 Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Covered Person (and those of the Covered Person's spouse and dependent children) that reasonably appears to be related to a research project:
 - 3.10.1 With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve 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 and any payment for services not otherwise identified as 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 reasonable measures of fair market value;
 - 3.10.2 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 twelve 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
 - 3.10.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- 3.11 Violations of this policy or proscribed management plans can lead to:
 - 3.11.1 Loss or restriction of privileges to conduct research
 - 3.11.2 Other employment actions as allowed by Human Resources Policies and Procedures.
- 3.12 Records related to disclosures and management of financial conflicts of interest are to be retained for at least three years from completion of the research.

4.0 RESPONSIBILITY

- 4.1 The COI Officer, IRB Office Staff and IRB carry out these procedures and ensures that a committee follows these procedures.
- 4.2 The COI Officer and/or IRB COI Committee reviews all financial disclosures for Covered Persons that reasonably appear to be related to a research project in which the Covered Person is engaged in at The Christ Hospital.

5.0 PROCEDURE

- 5.1 The COI Officer will initially review all affirmative financial interest disclosures of individuals participating in research. If a financial interest meets the definition of a SFI, then the COI Officer will review the individuals' research studies to determine if the SFI is related to or appears to be related to an existing research project.
 - 5.1.1 If the SFI relates to or appears to be related to a current research project involving human research and is an unreviewed disclosure or in amount greater than a previous disclosure for the research, it may be reviewed in the following manner:
 - 5.1.1.1 If the disclosure is less than \$25,000, then the COI Officer may perform the review and make a determination. However, if the COI Officer believes the IRB COI Committee needs to review the matter, it will be referred to the next convened IRB meeting.
 - 5.1.1.2 If the disclosure is greater than \$25,000, IRB COI Committee must perform the review and make a determination.
- 5.2 If the COI Officer can recommend a specific action (e.g., disclosure) based on monetary thresholds, then the COI Officer will notify the IRB Office staff in writing and the matter will be concluded with no subsequent steps of this procedure. The IRB Office staff document the action in the record and the IRB COI Committee is notified in the next Exempt/Expedited Report (Chairman's Report).
- 5.3 IRB COI Committee members who may have a conflict of interest with the research and/or the entity involving the financial interest will not participate in the review of the SFI and/or the determination of a financial conflict of interest.
- 5.4 The IRB COI Committee in collaboration with the COI Officer will determine whether the reported SFI is related to the research.
 - 5.4.1 If the SFI is not related to the research, the IRB Office Staff will document this determination in the meeting minutes and stop processing subsequent steps of this procedure.
- 5.5 The IRB COI Committee in collaboration with the COI Officer will determine whether the reported SFI could directly and significantly affect the design,

conduct, or reporting (i.e., the reported financial interest is a conflict of interest) of the Human Research.

- 5.5.1 If there is no conflict of interest, the IRB Office Staff will document this determination in the meeting minutes and stop processing subsequent steps of this procedure.
- 5.5.2 If a financial conflict of interests exists, the IRB COI Committee will determine if there should be any limitations on which activities the conflicted individual be allowed to participate in, including, but not limited to:
 - 5.5.2.1 Subject recruitment.
 - 5.5.2.2 Prescreening for inclusion/exclusion criteria.
 - 5.5.2.3 The consent process.
 - 5.5.2.4 The clinical treatment of subjects, separate from the research interventions or procedures.
 - 5.5.2.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.
 - 5.5.2.6 Evaluation of the clinical research data.
- 5.6 The IRB Office Staff will create a written management plan agreed to by the IRB COI Committee and the COI Officer. Potential stipulations may include, but are not limited to:
 - 5.6.1 Public disclosure of the financial interests.
 - 5.6.2 Disclosure of the financial interests to subjects.
 - 5.6.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest.
 - 5.6.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research, such as:
 - 5.6.4.1 precluding the conflicted researcher from obtaining informed consent from subjects, and/or
 - 5.6.4.2 reducing the researcher's role in the research (e.g., less interaction with subjects, less data analysis),
 - 5.6.5 Reduction or elimination of the financial interest (e.g., sale of an equity interest).
 - 5.6.6 Severance of relationships that create financial conflicts.
 - 5.6.7 Modification of the research plan.
 - 5.6.8 Involvement of external individuals in key portions of the protocol.
 - 5.6.9 Use of an external IRB.
 - 5.6.10 A plan to monitor and enforce the implementation of the management plan.
- 5.7 The IRB Office Staff will provide the written management plan to the conflicted researcher for comment and review. The conflicted researcher must agree to the terms.
- 5.8 Upon receipt of the conflicted researcher's agreement, the IRB Office Staff will finalize the written management plan.

- 5.9 If applicable, the reviewing IRB will be provided with the written management plan so the IRB can make the final decision as to whether the financial conflict of interest and its management, if any, allows the research to be approved. The IRB can add stipulations to the management plan but cannot remove any stipulations as required by the IRB COI Committee.
- 5.10 When applicable, provide written documentation that the research sponsor and/or regulatory agency has been notified of the management plan.
- 5.11 Maintain a copy of determinations and management plans in the records.

6.0 REFERENCES

- 6.1 IRB Standard Operating Procedure: SOP 2.13 Financial Disclosure
- 6.2 US Department of Health and Human Services (HHS) [42 CFR Part 50 Subpart F](#)
- 6.3 US Food and Drug Administration (FDA) [21 CFR Part 54](#)