



Public Health Service Investigator Conflict of Interest Policy

Background

Boston Children's Hospital ("Children's") is committed to protecting the integrity of its research and faculty by ensuring that relationships with industry are free of perceived or actual conflicts of interest. Accordingly, Children's Investigators are required to disclose their outside interests and activities pursuant to Children's Conflict of Interest Policy and Institutional Statement on Disclosure and Reporting of Conflicts [Please note that Children's Conflict of Interest Policy requires the disclosure of all financial interests, not just SFI, as defined under this Policy].

In August 2011, the Department of Health and Human Services ("HHS") amended the federal regulation governing financial conflicts of interest for research ("PHS Rules") funded by the Public Health Service. The regulation, as amended, enhances obligations related to Investigator disclosure of financial interests. They also set forth new requirements for Institutional identification and management of Investigators' financial conflicts of interest.

Policy

Purpose

This Policy sets forth Children's policy and procedures to implement the PHS Rules at Children's, including the disclosure of Significant Financial Interests and the management of Financial Conflicts of Interest, both as defined below.

Definitions

The definitions used in this Policy are derived from the PHS Rules.

Financial Conflict of Interest ("FCOI"): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. Note that the presence of an FCOI does not automatically disqualify an Investigator from conducting research; problems that may arise from FCOI can often be mitigated through identification of the conflict and effective institutional management.

Institutional Official: Vice President for Research Administration

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of Children's. Including but not limited to research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data Safety Monitoring Boards.

Investigator: The project director or principal investigator and any other person,



regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

Program Director/Principal Investigator (PD/PI): The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the applicant organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.

PHS Awarding Entity: Public Health Service of the U.S. Department of Health and Human Services, or by any of its component including but not limited to National Institutes of Health (NIH), National Cancer Institute (NCI), Centers for Medicare and Medicaid Services, Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA). Please refer to complete listing at <http://www.hhs.gov/about/orgchart/>.

PHS-funded research: Research funded in whole or in part by a PHS Awarding Entity.

Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by Children's in the grant application, progress report, or any other report submitted to the PHS by Children's. Other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition.

Significant Financial Interest ("SFI"): The definition of SFI is divided into (1) interests in entities and intellectual property interest and (2) sponsored travel.

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, an SFI 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;

- With regard to any non-publicly traded entity, an SFI 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
- Any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- (2) 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 their institutional responsibilities; provided, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Children's COI disclosure forms will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with Children's COI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

The term SFI does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by Children's to the Investigator if the Investigator is currently employed or otherwise appointed by Children's, including intellectual property rights assigned to Children's and agreements to share in royalties related to such rights.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical



center, or a research institute that is affiliated with an Institution of higher education.

General Policy Statement

Investigators are required to disclose their SFI no later than:

- at the time of application PHS-funded research, and
- within 30 days upon learning of or acquiring any new activities and interests, and
- annually throughout the duration of the PHS-funded research.

Upon receiving Investigators' disclosures, Institutional Officials will review the disclosures and determine whether any such disclosure meets the definition of an FCOI. Once an FCOI is identified, Institutional Officials will work with the Investigator to manage or eliminate the conflict.

Children's will provide mandatory training for all Investigators before they participate in PHS-funded research and periodically as required by the regulation. The training will include information on the PHS Rules, Children's and Harvard Medical School policies, and Investigator's disclosure responsibilities.

Procedure

1. Investigator Disclosure of Outside Activities and Interests

Investigators who do or plan to participate in PHS-funded research must disclose their SFIs no later than at the time of application for PHS-funded research. Once an Investigator is participating in PHS-funded research, the Investigator is required to continue to update their disclosure annually during the entire period of the federal award. Investigators participating in PHS-funded research must also update their disclosures within thirty (30) days of discovering or acquiring a new outside activity or interest. When updating one's disclosure, each Investigator must disclose all SFIs and be sure to include updated information regarding changes to previously disclosed SFIs.

Disclosures will be made through the Children's online disclosure system.

[Please note that Children's Conflict of Interest Policy requires the disclosure of all financial interests, not just SFI, as defined under this Policy].

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses an SFI or



an existing Investigator discloses a new SFI to Children's, the designated official(s) of Children's shall, within sixty (60) days: review the disclosure of the SFI; determine whether it is related to PHS-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, Children's may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of Children's review.

For any FCOI previously reported by Children's with regard to an ongoing PHS-funded research project, Children's shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. Children's shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component. Further, the annual reporting obligation to NIH must be done at the same time as when the grantee is required to submit to NIH the annual progress report, multi-year progress report, if applicable, or at time of grant extension.

2. Institutional Management of Financial Conflicts of Interest

a) Children's Investigators

Prior to Children's expenditure of any funds under a PHS-funded research project, the designated official(s) of Children's shall: review all Investigator disclosures of SFIs; determine whether any SFIs relate to PHS-funded research; determine whether an FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI.

Children's will work with Investigators to manage all identified FCOIs. Whenever Children's implements a management plan, Children's shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. Management of an FCOI may include actions such as disclosure of the financial interest, elimination of the interest altogether, modification of the research plan, and disqualification of personnel from participation in part or all of the research. Management strategies will be tailored to address the specific issues raised by each particular FCOI.

Prior to Children's expenditure of any funds under a PHS-funded research project, Children's shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by Children's to be conflicting and ensure that Children's has implemented a management plan. The report will include: (i) project number; (ii) PD/PI or contact PD/PI if a multiple PD/PI model is used; (iii) name of the Investigator with the FCOI; (iv) name of the entity with which the Investigator has an FCOI; (v) nature of the financial interest (*e.g.*, equity, consulting fee, travel



reimbursement, honorarium); (vi) value of the financial interest (dollar ranges); (vii) a description of how the financial interest relates to the PHS-funded research and the basis for Children's determination that the financial interest conflicts with such research; and (viii) a description of the key elements of Children's management plan, including: (A) role and principal duties of the conflicted Investigator in the research project; (B) conditions of the management plan; (C) how the management plan is designed to safeguard objectivity in the research project; (D) confirmation of the Investigator's agreement to the management plan; (E) how the management plan will be monitored to ensure Investigator compliance; and (F) other information as needed.

In cases in which Children's identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Children's shall not submit an FCOI report to the PHS Awarding Component.

For any SFI that Children's identifies as conflicting subsequent to Children's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Children's shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the FCOI and ensure that Children's has implemented a management plan.

As required by the PHS Rules, Children's will make available to the public, information concerning identified FCOIs of senior/key personnel within five (5) calendar days of the Institutional Official receiving a written request for such information. The publicly available information will include: (i) Investigator's name; (ii) the Investigator's title and role with respect to the research project; (iii) the name of the entity in which the SFI is held; (iv) the nature of the SFI; and (v) the approximate dollar value of the SFI, (or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value).

In any case in which the HHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Children's, Children's shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

b) Subrecipient Investigators

If Children's carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Children's must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

- Incorporating as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of Children's or that of the subrecipient will apply to the subrecipient's Investigators.



- If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of Children's for disclosing SFIs that are directly related to the subrecipient's work for the Institution;
 - Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOIs to Children's. Such time period(s) shall be sufficient to enable Children's to provide timely FCOI reports, as necessary, to the PHS;
 - Alternatively, if the subrecipient's Investigators must comply with Children's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to Children's. Such time period(s) shall be sufficient to enable Children's to comply timely with its review, management, and reporting obligations under this subpart.
- Providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

3. Investigator Training

Children's will provide regular training regarding this Policy and the PHS Rules ("Training") for all Investigators that will conduct PHS-funded research to educate them regarding their responsibilities under this Policy and the PHS Rules. Investigators cannot participate in research funded by PHS if they have not completed Training.

All Children's Investigators must complete Training prior to engaging in research related to any PHS-funded grant and upon any significant changes to this Policy. All Investigators must complete Training at least every four years. In addition, any Investigator who joins Children's faculty must complete Training prior to engaging in PHS-funded research. In the event that Children's finds that an Investigator is not in compliance with this Policy or a management plan, that Investigator must complete Training within one month of the finding, regardless of when the Investigator last completed regularly required Training.

4. Policy Compliance

a) Disciplinary Action

If the failure of an Investigator to comply with Children's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Children's shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the



matter to Children's for further action, which may include directions to Children's on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator. Additionally, the Institutional Official may suspend all of the Investigator's relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

b) Retrospective Review

Whenever Children's identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, including but not limited to an Investigator's failure to disclose an SFI that is determined to be an FCOI, or failure by an Investigator to materially comply with a management plan for an FCOI, was not previously reviewed by Children's during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Institutional Official(s) shall, within sixty (60) days: review the SFI; determine whether it is related to PHS-funded research; determine whether an FCOI exists; and, if so: The Institutional Official will refer the matter to the Office of General Counsel and Children's standing Research Conflict of Interest Committee, who will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research, within one hundred twenty (120) days of Children's determination of non-compliance. Additionally, Children's will implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with the PHS Rules, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

5. Record Retention

The Institutional Official Maintain records relating to all Investigator disclosures of financial interests and Children's review of, and response to, such disclosures (whether or not a disclosure resulted in Children's determination of a financial conflict of interest) and all actions under Children's policy or retrospective review, if



applicable, for at least three years from the date of the final expenditures report is submitted to the PHS.

6. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institutional Official may make such information available to an agency funding research of the faculty member, to a requestor of information concerning FCOI related to PHS or to the primary entity who made the funding available to Children's, if requested or required. If Children's is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of the disclosure.

7. Regulatory Authority

This Policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94.

Related Policies

The Conflict of Interest Policy:

Code of Conduct:

Institutional Review Board (IRB) Conflict of Interest Policy:

Harvard Medical School Policy on Conflicts of Interest and Commitment:

Institutional Statement on Disclosure and Reporting of Conflicts of Interest.

Document Attributes

Document Attributes

Title	Public Health Service Investigator Conflict of Interest Policy		
Author	Dianne McCarthy Alicia Christenson	Dates Reviewed/ Revised	4/29/15
Reviewed/ Revised by	Dianne McCarthy Suzanne Tannenbaum		
Copyright	©Boston Children's Hospital, 2015	Last Modified	
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