

Compliance Manual

Public Health Service Investigator Conflict of Interest Policy

I. General Policy Statement

Franciscan Children's Hospital ("FCH") is committed to protecting the integrity of its research and faculty by ensuring that outside relationships are free of perceived or actual conflicts of interest.

The FCH Conflict of Interest and Commitment Policy requires the disclosure of all financial interests and outside activities whether compensated or not, no later than:

- at the time of application for Public Health Service (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, designated official (s) will review the disclosures and determine whether any such disclosure meets the definition of a Significant Financial Interest (SFI). If FCH, through its designated officials(s), reasonably determines that an Investigator's SFI constitutes a Financial Conflict of Interest (FCOI), then FCH will work with the Investigator to manage or eliminate the conflict, including reporting and disclosure of any identified FCOI (s) to the PHS Awarding Entity.

This Policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94 and applies to each Investigator who is planning to participate in, or is participating in, PHS-funded research at FCH or at subrecipient institutions, domestic or foreign.

II. Purpose

This Policy sets forth FCH's policy and procedures to implement the PHS Rules at FCH, including the disclosure of SFIs and the management of FCOIs, both as defined below.

III. 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

General Counsel and Compliance Officer.

Institutional Responsibilities

An Investigator's professional responsibilities on behalf of FCH, 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 United States 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 FCH in the grant application, progress report, or any other report submitted to the PHS by FCH. 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 United States 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. FCH 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 FCH's Conflict of Interest policy, the designated 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 FCH's to the Investigator if the Investigator is currently employed or otherwise appointed by FCH, including intellectual property rights assigned to FCH 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 United States Federal, state, or local government agency, an Institution of higher education within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.
- Income from service on advisory committees or review panels for a United States Federal, state, or local government agency, an Institution of higher education within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

IV. 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 project 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.

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 FCH, the designated official(s) of FCH 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, FCH 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 FCH's review.

2. Institutional Management of Financial Conflicts of Interest

a) FCH Investigators

Prior to FCH's expenditure of any funds under a PHS-funded research project, the designated official(s) of FCH 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.

FCH will work with Investigators to manage all identified FCOIs. Whenever FCH implements a management plan, FCH 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 FCH's expenditure of any funds under a PHS-funded research project, FCH shall provide to the PHS Awarding Entity an FCOI report regarding any Investigator's SFI found by FCH to be conflicting and ensure that FCH has implemented a management plan. The report will include: (i) Grant 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, etc.); (vi) value of the financial interest (dollar ranges) or a statement that the value cannot be readily determined; (vii) a description of how the financial interest relates to the PHS-funded research and the basis for FCH's determination that the financial interest conflicts with such research; and (viii) a description of the key elements of FCH's management plan, including: (A) role and principle 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 FCH identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, FCH shall not submit an FCOI report to the PHS Awarding Entity.

For any SFI that FCH identifies as conflicting subsequent to FCH'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), FCH shall provide to the PHS Awarding Entity, within sixty (60) days, an FCOI report regarding the FCOI and ensure that FCH has implemented a management plan.

For any FCOI previously reported by FCH with regard to an ongoing PHS- funded research project, FCH shall provide to the PHS Awarding Entity 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. FCH shall provide annual FCOI reports to the PHS Awarding Entity for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Entity. 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.

As required by the PHS Rules, FCH 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; 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 FCH, FCH 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 FCH carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), FCH 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 FCH 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 FCH for disclosing SFIs that are directly related to the subrecipient's work for the Institution;

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 submit all Investigator disclosures of SFIs, and to report all identified FCOIs, to FCH. Such time period(s) shall be sufficient to enable FCH to provide timely FCOI reports, as necessary, to the PHS;

Providing FCOI reports to the PHS Awarding Entity 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

FCH requires 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 FCH 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 FCH’s faculty must complete Training prior to engaging in PHS-funded research. In the event that FCH 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 FCH’s FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, FCH shall promptly notify the PHS Awarding Entity of the corrective action taken or to be taken. The PHS Awarding Entity will consider the situation and, as necessary, take appropriate action, or refer the matter to FCH for further action, which may include directions to FCH 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 FCH 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 FCH during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), FCH 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 refer the matter to the Compliance Department and FCH standing Compliance Plan Oversight 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 FCH's determination of non-compliance. Additionally, FCH 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

FCH maintains records relating to all Investigator disclosures of financial interests and FCH's review of, and response to, such disclosures (whether or not a disclosure resulted in FCH's determination of a financial conflict of interest) and all actions under FCH 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 FCH, if requested or required. If FCH is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of the disclosure.

Related Policies and References

- Franciscan Children's Conflict of Interest Policy