



California Family Health Council Financial Conflict of Interest Policy for PHS Supported Research

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Approved By: Vice President of Research and Evaluation and
Vice President of Finance and Benefits Administration

I. Purpose, Scope and Applicability

The Federal Regulations at 42 CFR Part 50, Subpart F are designed to promote objectivity in research by establishing standards for Investigator disclosure of financial interests and institutional management of conflicts of interest, providing a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from Investigator conflicts of interest. These regulations require the California Family Health Council (CFHC) to maintain a written policy on financial conflicts of interest and to make the policy available on our publicly accessible website.

This policy applies to all California Family Health Council (CFHC) employees, including all full-time, part-time, temporary, contract employees and consultants, who are planning to participate in or are participating in Public Health Service ("PHS") funded research by means of a grant or cooperative agreement applied for by CFHC or issued to CFHC.

II. Definitions

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI Report means an Institution's report of a financial conflict of interest to a PHS Awarding Component (ex. NIH).

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the California Family Health Council (CFHC) including research, research consultation, outreach, clinical service, professional practice, education, and public service on behalf of CFHC which are in the course and scope of the CFHC appointment/employment.

Investigator means 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 research funded by the PHS or proposed for such funding, including collaborators, consultants, or contractors.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, in an effort to ensure that the design, conduct, and reporting of research is free from bias.

PHS, as used in this policy, means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). Research includes any activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program projects, or research training award.

Senior/key personnel means the Project Director/Principal Investigator and any other person identified as senior/key personnel by CFHC in the grant application, progress report, or any other report submitted to the PHS by CFHC.

Significant Financial Interest means

(1) A financial interest consisting of one or more of the following interests of the Investigator and the Investigator's spouse and dependent children that is related to sexual and reproductive healthcare or that otherwise might reasonably appear to be related to the Investigator's Institutional responsibilities:

(i) 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. Included are salary, consulting fees, honoraria, paid authorship, and stock, stock options, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value;

(ii) 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, and/or dependent children, holds any equity interest

(iii) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests that, when aggregated, exceeds \$5,000 in the twelve months preceding the disclosure.

(2) Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities if the known or reasonable assessed value when aggregated exceeds \$5,000 per entity in the 12 months preceding the disclosure. Sponsored travel is 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. In order to determine the disclosure threshold for sponsored travel, Investigators can determine a "reasonable assessed value" based on their own best estimate or they can request the actual value from the sponsoring entity. This disclosure requirement also applies to the Investigator's spouse and dependent children. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, a U.S. 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) The term *significant financial interest* does NOT include the following types of financial interests:

- Salary, royalties, or other remuneration paid by CFHC to the Investigator if the Investigator is currently employed or otherwise appointed by CFHC.
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, a U.S. institution of higher education, 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, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- 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.

III. Policy Implementation

A. Training Requirements

Each investigator, including collaborators, consultants and/or subcontractors, should be informed of CFHC's policy on financial conflicts of interest and should complete FCOI training prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter while receiving PHS research funding. Additional training should be provided as appropriate at the following other times in accordance with DHHS regulations: 1) CFHC revises its FCOI policy in any manner that affects the requirements of Investigators, 2) An Investigator is new to CFHC, or 3) CFHC finds that an Investigator is not in compliance with CFHC's FCOI policy or management plan. Qualifying FCOI training will be determined by the Manager of Regulatory Affairs and Quality Assurance and may include the NIH online FCOI tutorial, the CITI FCOI training, or FCOI training provided by another institution.

B. Disclosure of Significant Financial Interests

Investigators applying for or receiving PHS research funding are required to disclose *significant financial interests* related to their institutional responsibilities.

The presence of a *significant financial interest* under the terms of this policy, does not in and of itself imply the existence of an actual or potential financial conflict of interest.

Investigators shall disclose to CFHC all significant financial interests, including sponsored or reimbursed travel, related to their institutional responsibilities at the following times:

- No later than at the time of application for PHS funding;
- Before joining an ongoing PHS-funded research project
- Within 30 days of discovering or acquiring (eg. through purchase, marriage or inheritance) any new *significant financial interest*; and
- At least annually throughout the period of the PHS funded award.

It is the responsibility of the Principal Investigator to identify all Investigators on the project who are required to disclose significant financial interests (ie, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS).

For the purposes of this policy, a *significant financial interest* includes the occurrence of any reimbursed or sponsored travel with a known or reasonable assessed value, when aggregated, exceeding \$5,000 per entity in the 12 months preceding the disclosure. If future travel is planned at the time of disclosure that

will likely qualify as a significant financial interest once it has occurred, it can be reported in advance as part of the disclosure in order to avoid triggering the 30 day reporting requirement for a new significant financial interest in between annual reports.

At a minimum, the following information must be included as part of the disclosure of reimbursed or sponsored travel:

- purpose of the trip
- identity of the sponsor/organization
- destination
- duration
- known or estimated value of travel

CFHC travel reimbursement forms can be used for reporting of CFHC sponsored travel.

A FCOI Specialist designated by the Manager of Regulatory Affairs and Quality Assurance, will review the disclosure of sponsored or reimbursed travel and will determine if further information is needed from the Investigator.

Collaborators from other institutions who share responsibility for the design conduct or reporting of research results, and who will be conducting research under a subcontract or a memorandum of understanding (MOU) from CFHC, must comply with CFHC's FCOI policy and procedures. However, if the subrecipient institution has a conflict of interest policy that complies with DHHS regulations, it may be determined by the Manager of Regulatory Affairs and Quality Assurance that they can comply with the policies and procedures for disclosure and review of significant financial interests at the institution at which they are employed. In this situation, the subrecipient institution must notify CFHC of any identified conflicts and the subrecipient institution's plans to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements. A written agreement with the subrecipient institution or the collaborator must document whether the collaborator is expected to comply with CFHC's FCOI policy or that of the institution at which they are employed.

Collaborators who share responsibility for the design, conduct, and reporting of research results and who will participate in research under an independent consulting agreement issued by CFHC, must comply with the CFHC FCOI policy and complete the CFHC disclosure form.

C. Review of Disclosures and FCOI Management Plan

With each PHS proposal, progress report, incremental funding or extension, Investigators' *significant financial interests* disclosures will be reviewed by the FCOI Specialist to determine whether there are any *significant financial interests*

that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged.

If the FCOI Specialist concludes that an Investigator's *significant financial interest* has the potential to directly and significantly affect the design, conduct or reporting of the PHS-funded research, or is in an entity whose financial interests could be affected by the research, the disclosure and appropriate documentation will be forwarded to the Manager of Regulatory Affairs and Quality Assurance for consideration. The input of the disclosing Investigator will be sought and considered as part of this review. When it is determined that there is a FCOI, the Manager of Regulatory Affairs and Quality Assurance should make a final recommendation to the Vice President of Research and Evaluation and the Vice President of Finance and Benefits Administration about whether any conditions or restrictions should be placed on the conduct of the project to eliminate or manage the FCOI before the support can be accepted or ASAP during the course of a project. The final decision on FCOI management will be made by the Vice President of Finance and Benefits Administration in consultation with the Vice President of Research and Evaluation.

A management plan should be developed and implemented for all identified FCOIs. The management plan should specify the actions that are required to manage the FCOI, including:

- The role and principal duties of the conflicted Investigator
- Conditions of the management plan
- How the plan will safeguard objectivity in the research activity
- Confirmation of the Investigator's agreement to the plan, and
- How the plan will be monitored

If a significant financial interest is held by the senior/key personnel as defined in this policy, and it is determined to be a FCOI, CFHC will ensure public accessibility of information related to that SFI. Specifically, the information will be available by written response to any requestor within five business days of the request. The written response will include, at a minimum: the Investigator's name, the Investigator's title and role with respect to the research project, the name of the entity in which the SFI is held, the nature of the SFI, and 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.

D. Reporting to PHS

Prior to CFHC's expenditure of any funds provided under a PHS award, CFHC must provide to the PHS funding agency an initial report regarding Investigator

FCOI. If all FCOI are eliminated before research funds are expended, CFHC is not required to submit a report to the PHS funding agency.

During the period of the award, CFHC shall, within 60 days of receipt of disclosure of a new or newly discovered significant financial interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a FCOI, and if so, implement a management plan and report the FCOI to the PHS funding agency.

For any FCOI that CFHC reports to a PHS funding agency, CFHC shall provide to the PHS funding agency an annual FCOI report that addresses the status of the conflict and any changes to the management plan. The annual report should specify whether the FCOI is still being managed or explain why it no longer exists.

Within 60 days of determining that a FCOI exists for a new or new Investigator who joins an ongoing PHS-funded research activity, CFHC must implement a management plan and submit a report to the PHS funding agency.

If the DHHS determines that a PHS-sponsored project of clinical research whose purpose is to determine the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by CFHC as required by this policy and Federal regulation, CFHC shall require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

E. Retrospective Reviews and Mitigation Reports

When CFHC identifies a significant financial interest that was not disclosed in a timely manner by an Investigator or that was not previously reviewed during an ongoing PHS funded research project, the FCOI Specialist must do the following within 60 days:

- review the significant financial interest to determine whether it reasonably appears to be related to the PHS-funded research activity
- if so, forward the information to the Manager of Regulatory Affairs and Quality Assurance to determine whether a FCOI exists (see section C above for full process)

If it is decided that a FCOI exists, a management plan will be implemented as described in section C (Review of Disclosures and FCOI Management Plan).

In addition, whenever a FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose the significant financial interest that was determined to be a FCOI, or the Investigator did not comply with

an established management plan, CFHC must complete a retrospective review of the Investigator's activities and the PHS-funded research, within 120 days of the determination of non-compliance. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct, or reporting. CFHC will document the retrospective review. Such documentation will include the project number, project title, name of Investigator with the FCOI, name of the entity with which the Investigator has a FCOI, the reasons for the retrospective review, findings and conclusions.

Based on the results of the retrospective review, the previously submitted FCOI report should be updated (if appropriate) to specify the actions that CFHC will take to manage the FCOI going forward.

If bias was found during the retrospective review, CFHC will promptly notify the PHS funding agency and will draft a mitigation report that, at a minimum, documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines CFHC's plans to eliminate or mitigate the effect of the bias.

F. Records

As required by Federal regulation, CFHC shall maintain all records relating to Investigator disclosures of financial interests and CFHC's review of and response to such disclosures and all actions under CFHC's policy or retrospective review for at least 3 years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45CFR74.53(b) and 92.42(b) for different situations.