

Child Health and Development Institute of Connecticut, Inc.

Financial Conflict of Interest Policy for Investigators Participating in Public Health Services (PHS)-Funded Research

October 2021

Policy Statement

This policy is designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from investigator financial conflicts of interest (FCOI) pursuant to 42 C.F.R. Part 50 and 45 C.F.R. Part 94.

This policy, although formulated specifically for PHS funded research, also applies to any and all research regardless of the funding source, unless specifically stated otherwise herein.

This policy does not apply to Phase I support under the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Definitions

- **Committee** means CHDI's FCOI Disclosure Review Committee, which will be formed on an adhoc basis when a financial conflict of interest is disclosed by a CHDI employee or subrecipient/subcontractor. The Committee reviews and makes determinations of FCOIs.
- **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 and research funded by any other source.
- **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
- **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying, or that receives, PHS research funding or research funding from any other source.
- **Institutional responsibilities** mean an investigator's professional responsibilities on behalf of CHDI which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards.
- **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 sponsor, or proposed for such funding, which may include, for example, collaborators or consultants.
- **Manage** means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of PHS to which the authority involved may be delegated, including, but not limited to the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers

for Disease Control and Prevention (CDC) and the Health Resources & Services Administration (HRSA) .

- **Research** means a systematic investigation, study or experiment, including research development, testing and evaluation, 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).
- **Significant financial interest (SFI)** means:
 - 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.
 - **Remuneration** (e.g., salary, consulting fees, honoraria, and paid authorship) received from a **publicly traded entity** during the twelve-month period preceding the disclosure, and/or the value of any **equity interest** (e.g., stock, stock option, or other ownership interest) in such entity as of the date of disclosure, if the aggregated value of such remuneration and/or equity interest exceeds \$5,000.
 - **Remuneration** (e.g., salary, consulting fees, honoraria, and paid authorship) received from a **non-publicly traded entity** during the twelve-month period preceding the disclosure if the aggregated value of such remuneration and/or equity interest exceeds \$5,000.
 - Any **equity interest** (e.g., stock, stock option, or other ownership interest) in a **non-publicly traded entity**, regardless of value
 - Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
 - With regard to any **reimbursed or paid travel**, investigators must also disclose such travel related to their institutional responsibilities if the value of such travel when aggregated, exceeds \$5,000 from any single entity; except for travel that is reimbursed or paid by a Federal, state, or local government agency, an institute of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institute of higher education.
 - The **term significant financial interest does not include** the following types of financial interests:
 - Salary, royalties, or other remuneration paid by CHDI to the investigator if the investigator is currently employed or appointed by CHDI;
 - 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; or
 - Income from seminars, lectures, or teaching engagements sponsored by, or from service on advisory committees or review panels for, a federal, state, or local government agency, an institute of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institute of higher education.
- **Sponsor** means the entity or organization that provides PHS funds or any other funds for research, whether that be PHS or another institution where CHDI is the subrecipient of PHS-funded research or any other research funding.

Disclosure, Review, and Management of Conflicts:

A. Disclosure Process

Investigators have an ongoing responsibility to disclose, in writing, all SFIs. In considering whether an interest should be disclosed, the investigator should consult the definition of SFI within this policy and, if in doubt, resolve in favor of disclosure. Investigators will cooperate in good faith to provide the necessary information needed to ensure timely review.

SFIs must be disclosed on the following timelines:

- Investigators planning to participate in sponsored research must disclose any SFIs prior to submitting a sponsor proposal.
- New investigators joining existing sponsored research must disclose any SFIs prior to participating in sponsored research
- Investigators participating in sponsored research must submit an updated disclosure annually during the period of any sponsor award.
- Investigators participating in sponsored research must submit an updated disclosure of SFIs within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance, etc.) a new SFI.

Details of a disclosure must be sufficient to allow the Committee to perform an assessment and review. Details of a disclosure related to sponsored or paid travel must include the purpose and duration of the trip, the identity of the sponsor/organizer, and the destination.

All disclosures shall be submitted to the Chief Executive Officer, who in turn will appoint an adhoc FCOI Disclosure Review Committee to review such disclosure.

B. Review of Disclosures

The Committee is under the supervision of and reports to the President and Chief Executive Officer (CEO) of CHDI.

Upon receipt of a disclosure of an SFI, the Committee will perform a review and determine whether the SFI constitutes an FCOI. In the course of reviewing an SFI, the Committee will determine how the SFI is tied to activities within the investigator's institutional responsibilities. An SFI becomes a FCOI when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of the sponsored research. The Committee will complete the review, make a determination as to whether an FCOI exists, and, if so, promptly report such FCOI to the CEO and the CHDI Board of Directors, develop a management plan within sixty (60) days of receiving the investigator's disclosures and prior to any expenditure of funds for the sponsored research affected by the FCOI.

In its review, the Committee may employ and seek further assistance and clarification from the investigator or other CHDI employees whose knowledge and skills relate to the research. In addition, the Committee is authorized to request from the investigator any other information it deems necessary to assist in its determination.

C. Management of Conflicts

If the Committee determines a FCOI exists, the staff member (or subcontractor) disclosing the significant financial interest (also known as the investigator), the investigator's manager, if any, and the CEO of CHDI must develop a management plan. The Committee will review the management plan and will either approve or add conditions or restrictions to ensure the FCOI is managed. Conditions or restrictions that may be imposed may include the following:

- Public disclosure of FCOIs (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of FCOIs directly to participants;
- Monitoring of the research by independent reviewers;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of investigator from participation in all or a portion of the research;
- Sale or divestiture of the SFI (e.g., sale of an equity interest); or
- Severance of relationships that create FCOIs.

Investigators must comply with all elements and conditions of their management plan and may be required to provide documentation of compliance to all or some elements, such as in the case of sale or divestiture of an FCOI. The Committee shall monitor compliance.

D. FCOI Reporting

When an FCOI exists, the FCOI must be reported to the sponsor in a timely manner prior to expending any funds under the sponsored research project. If the Committee identifies a FCOI and eliminates it prior to the expenditure of any funds, CHDI is not required to submit a FCOI report to the sponsor, unless a sponsor specifically requires such FCOI reporting regardless of fund expenditure timelines. Reports shall include, but are not necessarily limited to, the following: (1) project number; (2) name of investigator managing the project; (3) name of investigator with FCOI; (4) name of entity with which investigator has FCOI; (5) nature of financial interest; (6) value of financial interest or statement that value is not readily determined; (7) description of how financial interest relates to sponsored research and basis for determination of FCOI; and (8) description of the key elements of the management plan.

If CHDI identifies a FCOI subsequent to the expenditure of funds for the sponsored research, CHDI will file an FCOI report with sponsor within forty-five (45) days of the identification of the FCOI.

For any FCOI previously reported with regard to an ongoing sponsored research project, CHDI shall provide to the sponsor an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the sponsored research project.

E. Retrospective Review

Whenever a FCOI is not identified or managed in a timely manner, including failure by the investigator to disclose a SFI that is determined to be a FCOI, failure by CHDI to review or manage such a FCOI, or failure by the investigator to comply with a FCOI management plan, the Committee shall, within 120 days of the determination of noncompliance, complete a

retrospective review of the investigator's activities and the sponsored research project to determine whether any sponsored research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

Each retrospective review shall be documented and shall include at least the following elements: (1) project number; (2) project title; (3) name of investigator managing the project; (4) name of investigator with FCOI; (5) name of entity with which investigator has FCOI; (6) reasons for retrospective review; (7) detailed methodology used for retrospective review; (8) finds of review; and (9) conclusions of review.

Based on the results of the retrospective review, if appropriate, the Committee shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Committee shall notify the sponsor promptly and submit a mitigation report to the sponsor. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and CHDI's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Other Management and Administration Responsibilities:

A. Public Disclosures

CHDI shall maintain this policy on its publicly available website.

Public requests to review FCOIs must be made in writing and should include sufficient information to allow CHDI to identify the requestor, where the information should be sent, and the investigator whose FCOI information is requested.

All public requests should be directed to the following address:

Jeffrey J. Vanderploeg, Ph.D.
President and Chief Executive Officer
Re: Financial Conflict of Interest – Public Disclosure
Child Health and Development Institute of Connecticut, Inc.
270 Farmington Ave., Suite 367
Farmington, CT 06032

CHDI must provide the requested information within 5 business days of receiving a request. Only those FCOIs that have been disclosed and continue to be held need be publicly disclosed.

B. Employee Training and Compliance

CHDI will include this FCOI Policy within its Code of Ethics and Conduct Policy to inform investigators and all employees about this policy, 42 C.F.R. Part 50 and 45 C.F.R. Part 94, and the investigator's responsibilities regarding disclosure of SFIs. On an annual basis, all employees will be required to certify in writing that they will comply with this FCOI Policy.

FCOI Policy training and compliance certification shall occur in the following circumstances:

- Prior to an investigator engaging in sponsored research (training provided by the investigator's manager)

- When an employee is newly hired by CHDI (training during orientation)
- When CHDI revises this policy in a manner that affects the requirements of investigators
- When the investigator is not in compliance with this policy or an approved management plan (training provided by the Committee)
- At least every 4 years (training accomplished via annual FCOI policy review and certification)

C. Enforcement

Failure to properly disclose relevant financial and other interests or to adhere to any management plan imposed by the Committee will be considered failure to meet the acceptable standards of conduct of CHDI and may subject the investigator to appropriate enforcement actions in accordance with CHDI's policies for employees or subcontractors.

D. Subrecipient Investigators

If any portion of the sponsored research is funded via the PHS and is performed by a subrecipient (and/or subcontractor), CHDI will enter into a written agreement with the subrecipient institution or investigator confirming that:

- The subrecipient institution's FCOI policy complies with 42 C.F.R. Part 50 and 45 C.F.R. Part 94 and, further, that the subrecipient will report identified FCOIs for investigators to CHDI within twenty (20) days so that CHDI has sufficient time to report those FCOIs to the sponsor; or
- If the subrecipient lacks a compliant FCOI policy, the subrecipient investigator will be governed by this policy, which shall be included as an exhibit in the subrecipient's contract.

If any portion of the sponsored research is funded by any source other than the PHS and is performed by a subrecipient (and/or subcontractor), CHDI will enter into a written agreement with the subrecipient institution or investigator confirming that:

- The subrecipient institution's FCOI policy complies with this policy and, further, that the subrecipient will report identified FCOIs for investigators to CHDI within twenty (20) days so that CHDI has sufficient time to report those FCOIs to the sponsor; or
- If the subrecipient lacks a compliant FCOI policy, the subrecipient investigator will be governed by this policy, which shall be included as an exhibit in the subrecipient's contract.

E. Maintenance of Records

The Committee will maintain and retain all information, records and reports collected and prepared under this policy for at least three (3) years from the date of the final expenditure reports for the sponsored research project, or longer as required by the applicable law or CHDI's record retention policy.