

Total Child Health, Inc,
Financial Conflict of Interest Policy (FCOI)
Effective Date: June 17, 2020

Policy Summary

By law, all Investigators applying for and working on Public Health Services (PHS), National Institutes of Health (NIH), or National Science Foundation (NSF) funded research must disclose significant financial interests (SFIs) that are related to the Investigator's institutional responsibilities. Investigators are ALL persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS, NIH, or NSF, including collaborators or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

Definitions/Glossary

Disclosure of significant financial interests – an Investigator's disclosure of significant financial interests to an Institution.

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

FCOI report – an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest – anything of monetary value, whether or not the value is readily ascertainable.

HHS – the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

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 research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage – taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI – a project director or principal Investigator of a PHS-funded research project.

PHS – 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 – 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). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel – the PD/PI and any other person identified as senior/key personnel by Total Child Health, Inc. in the grant application, progress report, or any other report submitted to the PHS by Total Child Health, Inc..

Significant financial interest –

(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:

(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. 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;

(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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must 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, however, 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. Investigator recipients of sponsored travel are required, at minimum, to disclose

the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. President or appropriate official within the Office of the Provost 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.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by Total Child Health, Inc. to the Investigator if the Investigator is currently employed or otherwise appointed by Total Child Health, Inc., including intellectual property rights assigned to Total Child Health, Inc. 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; or 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.

This Policy Applies to: ALL persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS/NIH/NSF, including collaborators or consultants.

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|---|
| <input checked="" type="checkbox"/> Independent Contractors |
| <input checked="" type="checkbox"/> Staff |
| <input checked="" type="checkbox"/> Consultants |

Reason(s) for the Policy

Total Child Health, Inc. is required, by federal law (C.F.R. Part 50 Subpart F), to comply with regulations pertaining to Financial Conflicts of Interest in government-funded research. As an institution that regularly competes for and receives federal funding for research, Total Child Health, Inc. is required to have a written and enforced policy on conflict of interest.

The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS), National Institute of Health (NIH), National Science Foundation (NSF) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The policy further provides a mechanism for all conflicts of

interest for each award to be managed, reduced or eliminated prior to the expenditure of the award funds.

Policy

President will inform each Investigator of Total Child Health, Inc.'s policy on financial conflicts of interest, the Investigator's responsibilities regarding timely disclosure of significant financial interests, and federal regulations governing federally funded research prior to submitting an application to a federal funding agency.

Investigator Responsibilities

Each Investigator who is planning to participate in the PHS/NIH/NSF-funded research must disclose to President the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS/NIH/NSF-funded research. Investigators must complete the appropriate Financial Disclosure Form found in the appendix of this policy (either the PHS/NIH or NSF specific form). Any Investigator who is participating in any PHS/NIH/NSF-funded research must submit an updated disclosure of significant financial interest at least annually during the period of the award.

In the event a financial conflict of interest arises during the period of the award, the Investigator is required to notify President within thirty days of discovering or acquiring a new significant financial interest.

Investigators are required to complete training prior to engaging in research related to any PHS/NIH-funded grant and at least every four years thereafter. Training is also required in cases where an Investigator is new to Total Child Health, Inc. and continues to serve as an Investigator in a funded project transferred from another institution to Total Child Health, Inc.. Refresher training is required in the event an Investigator is not in compliance with Total Child Health, Inc.'s financial conflict of interest policy or management plan. Financial conflict of interest training is administered and available through President or the Office of the Provost. Investigators applying for funding from NSF or any other federal agency are encouraged to complete financial conflict of interest training.

Investigators Engaged in Subrecipient Research or Engaging Others as Subrecipients

Faculty and staff engaged in funded research as a subrecipient may be required by the awardee institution to comply with the awardee institution's own financial conflict of interest policy. Likewise, in cases where Total Child Health, Inc. serves as the awardee institution in PHS/NIH/NSF-funded research projects, Total Child Health may require subrecipients to comply with Total Child Health's financial conflicts of interest policy. In these cases, the awardee institution or subrecipient and Total Child Health, Inc. must incorporate, in a written agreement, whether the financial conflicts of interest policy of the awardee institution or that of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with applicable law. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by law. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee institution. Such time period(s) shall be sufficient to enable the awardee institution to comply timely with its review, management, and reporting obligations under the law.

Significant Financial Interests Identified

President is designated as Total Child Health, Inc.'s institutional official to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS/NIH/NSF-funded research as detailed above. In the event the Investigator discloses a significant financial interest, a management plan will be created and supervised by a non-conflicted person, the Senior Project Manager.

An Investigator's significant financial interest is related to PHS/NIH/NSF-funded research when Total Child Health, Inc., through its designated officials, reasonably determines that the significant financial interest: could be affected by the PHS/NIH/NSF-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when Total Child Health, Inc., through its designated officials, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS/NIH/NSF-funded research.

Financial Conflict of Interest Identified

In cases where the Financial Conflict of Interest Committee identifies a financial conflict of

interest, the Senior Project Manager is tasked with taking such actions as necessary to manage the financial conflict of interest. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to §50.605(a). Additionally, the Senior Project Manager must comply with, and provide, initial and ongoing FCOI reports to the PHS as required pursuant to §50.605(b).

The Senior Project Manager must maintain records relating to all Investigator disclosures of financial interests and Total Child Health, Inc.'s review of, and response to, such disclosures (whether or not a disclosure resulted in Total Child Health, Inc.'s determination of a financial conflict of interest) and all actions under Total Child Health, Inc.'s policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

Management of Financial Conflicts of Interest

The Financial Conflict of Interest Committee is required to develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage financial conflicts of interest when they arise. The following examples are conditions or restrictions that may be imposed by the Senior Project Manager to manage a financial conflict of interest, but they are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) 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;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

Penalties and Enforcement

Federal regulations require Total Child Health, Inc. to impose sanctions or take other administrative actions where appropriate. Total Child Health maintains the right to impose sanctions on Investigators for failure to disclose significant financial interests and for failure

to abide by this policy. Sanctions may include restrictions on future submission of research proposals and other disciplinary actions up to and including dismissal in accordance with the employee handbook.

Confidentiality

Except to the extent required by law and federal regulations, the information disclosed throughout these processes will be kept confidential. Total Child Health, Inc., however, is required to report the existence of real or potential conflicts of interest to certain federal agencies.

Reporting of Financial Conflicts of Interest

Prior to Total Child Health, Inc.'s expenditure of any funds under a PHS-funded research project, Total Child Health, Inc. shall, consistent with §50.604(f): review all Investigator disclosures of significant financial interest; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest 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 financial conflict of interest.

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to Total Child Health, Inc., the Senior Project Manager shall, within sixty days: review all Investigator disclosures of significant financial interest; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest 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 financial conflict of interest.

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by Total Child Health, Inc. to constitute a financial conflict of interest; failure by Total Child Health, Inc. to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, Total Child Health, Inc. shall, within 120 days of Total Child Health, Inc.'s determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

Total Child Health, Inc. is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed

methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, Total Child Health, Inc. shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, Total Child Health, Inc. is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. 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 Total Child Health, Inc.'s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Total Child Health, Inc. will submit FCOI reports annually, as specified elsewhere in the policy. Depending on the nature of the financial conflict of interest, Total Child Health, Inc. may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of Total Child Health, Inc.'s retrospective review.

Whenever Total Child Health, Inc. implements a management plan pursuant to this policy, Total Child Health, Inc. shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to Total Child Health, Inc.'s expenditure of any funds under a PHS-funded research project, Total Child Health, Inc. shall ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to Total Child Health, Inc. that meets the following three criteria: (A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart; (B) Total Child Health, Inc. determines that the significant financial interest is related to the PHS-funded research; and (C) Total Child Health, Inc. determines that the significant financial interest is a financial conflict of interest.

The information that Total Child Health, Inc. makes available via a written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (the following dollar ranges will be used: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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.

The written response will contain a note that "the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within

60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.”

Additional Reporting Requirements

Prior to Total Child Health, Inc.'s expenditure of any funds under a PHS-funded research project, Total Child Health, Inc. shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by Total Child Health, Inc. to be conflicting and ensure that Total Child Health, Inc. has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, Total Child Health, Inc. shall not submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that Total Child Health, Inc. identifies as conflicting subsequent to the Institution'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), Total Child Health, Inc. shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), Total Child Health, Inc. also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, Total Child Health, Inc. is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report required under this policy shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Total Child Health, Inc.'s management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following: (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 financial conflict of interest; (iv) Name of the entity with which the Investigator has a financial conflict of interest; (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) Value of the financial interest (dollar ranges will be used: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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; (vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and (viii) A description of the key elements of the Institution'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.

For any financial conflict of interest previously reported by Total Child Health, Inc. with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest 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 financial conflict of interest no longer exists. Total Child Health, Inc. 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.

Exclusions and Special Situations

Not applicable

Policy Contact(s)

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Policy History

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