



FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

INTRODUCTION

This policy governing financial conflict of interest applies to all Public Health Service (PHS)-sponsored Investigators of the Coalition for National Trauma Institute (CNTR) (the Institution). CNTR's Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

DEFINITIONS

Associate means all Regular and Term employees, graduate school students, and sponsored fellows at CNTR.

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

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.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental

agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or

- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, **Financial Interest** also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Institutional Official means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the CNTR Institutional Official is designated as Amy Flores, Controller.

Institutional responsibilities means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. The definition may also include collaborators or consultants as appropriate. For the purposes of this policy, the following individuals at CNTR are considered Investigators when they are responsible for the design, conduct, or reporting of research funded by the PHS:

- a) Principal Investigators
- b) Co-Investigators
- c) Key Personnel

Public Health Service or **PHS** 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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the following agencies:

- a) Agency for Healthcare Research and Quality (AHRQ)
- b) Agency for Toxic Substances and Disease Registry (ATSDR)
- c) Centers for Disease Control and Prevention (CDC)
- d) Food and Drug Administration (FDA)

- e) Health Resources and Services Administration (HRSA)
- f) Indian Health Service (IHS)
- g) National Institutes of Health (NIH)
- h) Office of the Assistant Secretary for Health (OASH)
- i) Office of the Assistant Secretary for Preparedness & Response (ASPR)
- j) Office of Global Affairs (OGA)
- k) Substance Abuse and Mental Health Services Administration (SAMHSA)

Research means a systematic investigation, study, or experiment designed to 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 means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

OVERVIEW

The United States Department of Health and Human Services has issued regulations pertaining to financial conflicts of interest. The regulations require that all individuals who participate in the design, conduct, or reporting of research funded by the Public Health Service (PHS) agencies complete training on financial conflicts and disclose personal financial interests that could give rise to an actual conflict of interest or the appearance of a conflict. See the full text of the regulations and the final rule implementing the regulations published in the Federal Register for more information.

The requirements of this Policy should be read in conjunction with CNTR's Conflict of Interest Policy, which provides general instruction on preventing, recognizing, and mitigating conflicts of interest.

RESPONSIBILITIES

- 1) **Investigators** are responsible for completing all required training, disclosing all Financial Interests relating to PHS-funded research, for mitigating risks associated with

Significant Financial Interests, and for assisting with the management of any identified FCOI.

- 2) The **Institutional Official** is responsible for reviewing all disclosed Financial Interests to identify any Significant Financial Interests to determine if they may represent an FCOI. All disclosed Financial Interests shall be reviewed by the Institutional Official and the Institutional Official shall provide guidance to the Investigator and to CNTR's Board of Directors with respect to Significant Financial Interests that may give rise to FCOI. Upon identification of potential FCOI related to a project funded by PHS, the Institutional Official will work with the Investigator and the relevant research manager to manage the FCOI.
- 3) **Contracts & Grant Services** is responsible for taking reasonable steps to ensure that subcontractors comply with the Department of Health and Human Services Financial Conflict of Interest regulations.
- 4) All **CNTR Associates** will comply with regulatory requirements relating to our Institutional Responsibilities, including certification of compliance, maintenance of records, responses to requests for information, and reporting requirements.

CONFLICT OF INTEREST

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the Institution on an annual and on an ad hoc basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by March 1 for the previous calendar year.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) **Travel**

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2) **RELEVANT FINANCIAL INTERESTS**

The following Financial Interests may potentially qualify as Significant Financial Interests:

- a) **Remuneration** (including salary, wages, consulting fees, honoraria, and any other fee for services)
- b) **Defined benefit pension payments** or other post-employment payments
- c) Service in a **management position** such as a board member, director, officer, partner, or trustee of a Healthcare-Related Entity
- d) Ownership of an **equity interest** (including stock, stock options, bonds, or any other ownership interest)
- e) Holdings in a **healthcare sector-oriented mutual fund**
- f) **Intellectual property rights** (e.g., patents or copyrights) from which income is received
- g) **Gifts** of more than nominal value (more than \$20) from clients, vendors, or Healthcare-Related Entities
- h) Reimbursed or sponsored **travel** related to an Investigator's Institutional Responsibilities
 - a. Sponsored travel means travel expenses paid on behalf of an Investigator (or relevant family member) rather than paid by reimbursement

- b. Travel reimbursed or sponsored by the following is excluded: federal, state, or local government agencies; institutions of higher education; academic teaching hospitals; medical centers; and research institutes affiliated with institutions of higher education.
- c. Investigators will be required to provide the following information with respect to any reimbursed or sponsored travel: name of entity that sponsored or reimbursed any expenses associated with the trip; purpose of the trip; destination; date and duration of the trip; and amount of reimbursement received.

Excluded Financial Interests

The following Financial Interests do not give rise to Significant Financial Interests and therefore need not be disclosed:

- a) Salary, wages, and remuneration paid by CNTR
- b) Travel expenses paid or reimbursed by CNTR
- c) Income from mutual funds and retirement accounts (other than healthcare sector-oriented funds, see Section 4.2(e) above), as long as the Investigator does not directly control the investment decisions made by the funds
- d) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education
- e) Service on advisory committees or review panels for a federal, state, or local government agency; an 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) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. As described in the PHS regulations, some examples of how financial conflicts of interest may be addressed and managed include:

- a) Public disclosure of an Investigator's Significant Financial Interests; disclosures will only occur after notice to and consultation with the Investigator
- b) Disclosure of FCOI directly to participants in Research projects involving human subjects

- c) Monitoring of Research projects by reviewers who do not have FCOI and who are capable of implementing measures to protect the design, conduct, or reporting of the Research against bias arising from identified FCOI
- d) Modification of the research plan, including, for example, change of personnel or personnel responsibilities with respect to particular tasks
- e) Disqualification of personnel from participation in all or a portion of a Research project funded by PHS or CMS
- f) Reduction or elimination of a Significant Financial Interest (e.g., sale of stock)
- g) Severance of relationships (e.g., consulting activities) that create actual or potential conflicts.

If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

4) CLINICAL TRIALS

Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

5) REPORTING TO PHS

The institutional official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

6) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented. The Institutional Official must implement a management plan within sixty days whenever the official identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution.

The Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b) Retrospective Review

If the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official will complete a retrospective review of the Investigator's activities and the PHS-sponsored 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. Retrospective reviews will be completed and documented within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner.

The Institutional Official will document these reviews consistent with the regulation. Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, 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 the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the

retrospective review, 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.

c) Clinical Trials

In any case in which the Department of Health and Human Services 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 the Institution as required by the regulation, the Institution shall require the Investigator involved to:

- a) Disclose the FCOI in each public presentation of the results of the research, and
- b) Request an addendum to previously published presentations and manuscripts.

7) MANDATORY TRAINING

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Each Investigator will receive a copy of this policy and complete CNTR's FCOI training at the time they join CNTR or prior to assuming an investigator role on a PHS application or PHS-funded project. As such, each investigator will be aware of their disclosure responsibilities and the relevant federal regulations.

8) SUBRECIPIENT COMPLIANCE AND REPORTING

When the Institution carries out PHS-funded Research through a sub-recipient (e.g., subcontractors or consortium members), the Institution will take reasonable steps to ensure that any sub-recipient Investigator complies with the FCOI regulations. The sub-recipient Institution may elect to have sub-recipient Investigator(s) governed by their Financial Conflict of Interest Policy provided they are in compliance with FCOI regulations, or the sub-recipient Institution may elect to have sub-recipient Investigator(s) governed by CNTR's PHS FCOI policy and these procedures.

The subcontract must include a statement clarifying whether the sub-recipient Institution or CNTR's PHS FCOI Policy and these procedures will govern the sub-recipient Investigator(s). If the sub-recipient Investigator(s) will be governed by the sub-recipient's Financial Conflict of Interest Policy and Procedures, the Sub-recipient must certify in the subcontract that their Financial Conflict of Interest Policy and Procedures comply with the PHS FCOI Regulations. The subcontract shall specify the time period(s) for the sub-recipient to report all identified Financial Conflicts of

Interest(s) to the Institution. Such time period(s) shall be sufficient to enable the Institutions to provide timely FCOI reports, as required, to PHS.

If the sub-recipient cannot provide such certification or elects to have the sub-recipient Investigators governed by the Institution's PHS FCOI Policy and Procedures, the subcontract shall state that sub-recipient Investigators are subject to the PHS FCOI Policy and Procedures of the Institution for disclosing Significant Financial Interests that are directly related to the sub-recipient's work for the Institution. The subcontract shall specify time period(s) for the sub-recipient to submit all Investigator disclosures of Significant Financial Interests to the Institution. Such time period(s) shall be sufficient to enable the Institution to comply timely with its review, management, and reporting obligations to PHS.

Alternatively, if applicable, the sub-recipient agreement will include a requirement to solicit and review sub-recipient Investigator disclosures that enable the awardee Institution to identify, manage, and report identified FCOI to the PHS.

Regardless of the governing Financial Conflict of Interest Policy and procedures for sub-recipient Investigators, the Institution will be responsible for providing FCOI reports to PHS regarding all Financial Conflicts of Interest of all sub-recipient Investigators, prior to the expenditure of funds and within sixty days of any subsequently identified FCOI.

9) REPORTING REQUIREMENTS TO PHS

Prior to the expenditure of any funds under a PHS-funded Research project, the Institution will submit an FCOI Report to PHS regarding any Investigator's Significant Financial Interest found by the Institutional Official to be conflicting. If the Institutional Official identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of PHS-awarded funds, an FCOI Report is not required to be submitted to PHS.

For any Significant Financial Interest that the Institutional Official 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), the Institutional Official shall provide to PHS, within sixty days, an FCOI report regarding the Financial Conflict of Interest.

The Institutional Official will promptly notify the PHS if bias is found with the design, conduct or reporting of NIH-funded research. This notification will include a Mitigation Report in accordance with the regulation (42 CFR 50.605(a)(3)(iii)). An FCOI Report fulfilling the requirements as stated above will include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's Management Plan. The report shall include, at a minimum, the project number; Project Director/Principal Investigator (PD/PI) or Contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the Financial Conflict of Interest; name of the Entity with which the Investigator has a Financial Conflict of Interest; nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium); value of the Financial Interest (dollar ranges

are permissible: \$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; 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 a description of the key elements of the Management Plan, including: role and principal duties of the conflicted Investigator in the Research project; conditions of the Management Plan; how the Management Plan is designed to safeguard objectivity in the Research project; confirmation of the Investigator’s agreement to the Management Plan; how the Management Plan will be monitored to ensure Investigator compliance; and other information as needed.

The Institutional Official will promptly notify PHS if an Investigator fails to comply with the Institution’s FCOI Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research. The Institutional Official is required promptly take corrective action for noncompliance with the Institution’s policy or management plan.

For any Financial Conflict of Interest previously reported by the Institution with regard to an ongoing PHS-funded Research project, the Institution shall provide to PHS 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 (including extensions with or without funds). 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.

10) MAINTENANCE OF RECORDS

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken. Records will be further retained from other dates specified in 45 CFR 75.361, where applicable.

11) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

12) PUBLIC ACCESSIBILITY

This policy will be publicly available on the Institution's website and uploaded into the eRA Commons IPF Module. Additional FCOI policy documents or modifications will be uploaded into the IPF Module on a timely basis to supplement and/or replace the one(s) previously submitted.

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation, be updated at least annually, or within sixty days of a newly identified FCOI and remain available for three years from the date the information was most recently updated.

13) REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.