

Communication Disorders Technology, Inc.

Financial Conflict of Interest Policy

Purpose

This FCOI policy is written to reflect compliance with the FCOI regulation at 42 CFR Part 50 Subpart F of the NIH Federal Public Health Service (PHS) regulations on Promoting Objectivity in Research, which promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator responsible for the research. This regulation is written to safeguard the public's trust in federally supported research that is conducted with the highest scientific and ethical standards. The regulation does not apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs Phase I applications/awards.

Definitions

Investigator

"Investigator" is defined as the Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, including persons who are subgrantees, contractors, consortium participants, collaborators, or consultants.

PHS Awarding Component

The organizational unit of the Public Health service (PHS) within Health and Human Services (HHS) which funds the investigator's research.

Research

"Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function.

Significant Financial Interest (SFI)

- 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.
- 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

- The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

Small Business Innovation Research (SBIR) - A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization.

Conflict of Interest Officer (COIO)

- Informs each investigator of CDT's FCOI policy and Investigator's disclosure reporting obligations, including timeframes for doing so
- Is responsible for determining the existence of conflicting interests and takes actions to ensure that they will be managed, reduced, or eliminated. Establishes adequate enforcement mechanisms and sanctions where appropriate
- Acts as contact point that Investigators and others may contact for questions and discussion
- Informs each Investigator of institution's COI policy
- Solicits and reviews financial disclosure statements from Investigators annually or as new reportable interests are obtained
- Ensures that records of all financial disclosures and all actions taken by the institution will be maintained for at least three years from the date of submission of the final expenditures report
- Ensures that, if Investigator has biased the research, the PHS awarding component is promptly notified of the corrective action taken or to be taken
- Ensures that, if HHS determines that a PHS-funded project to evaluate a drug, medical device or treatment was conducted by an investigator with a conflict that was not disclosed or managed, requires Investigators to disclose the conflict in each public presentation of the results of the research
- Ensures that CDT certifies, in each PHS application for funding, that:
 - CDT has in effect a written and enforced process to identify and manage, reduce, or eliminate conflicting interests
 - Prior to expending any funds under the award, CDT will report to the PHS Awarding Component the existence of a conflicting interest and assure that it has been managed, reduced, or eliminated, and, for any interest identified as conflicting subsequent to CDT's initial report, a report will be made, and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within 60 days; and

- Upon request, CDT agrees to make information available to HHS regarding all conflicting interests and how those interests have been managed, reduced, or eliminated.

Institutional Responsibilities

CDT's FCOI policy includes its responsibility to

- Maintain an up-to-date, written, enforced FCOI policy that complies with the regulation and making the policy publicly accessible. Additional responsibilities include, but are not limited to:
- Solicit and review disclosures of Investigators' SFIs that are reasonably related to an Investigator's institutional responsibilities
- Determine whether an Investigator's SFI is related to the NIH-funded research and, if so related, whether the SFI is a FCOI (SFI that could directly and significantly affect the design, conduct or reporting of the NIH-funded research)
- Develop and implement management plans, as needed to manage FCOIs for awardee Investigators and subrecipient Investigators, if applicable
- Submit initial and annual FCOI reports to the NIH in accordance with the regulation
- Complete retrospective reviews when there is noncompliance with the Institution's policy or the FCOI regulation and updating any previously submitted FCOI report, if required after the retrospective review is complete
- Submit mitigation reports when bias is found in NIH-supported research as a result of the finding from a retrospective review.

Training

CDT by its COIO shall inform each Investigator of Investigator responsibility for complying with the content of the NIH FCOI Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F) and shall require the completion of up-to-date Disclosure of Investigator's Significant Financial Interests (SFIs) (and those of their spouse and dependent children), as defined herein.

CDT by its COIO shall inform each Investigator of Investigator responsibility for complying with CDT FCOI policies and procedures, completing FCOI training prior to engaging in NIH-funded research and thereafter, every four years and immediately when any of the following circumstances apply: (i) the Institution revises its FCOI policies and procedures in any manner that affects the requirements of Investigators; (ii) an Investigator is new to an Institution; or (iii) an Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan; and for disclosing the required information to the Institution whether the Investigator is planning to participate in or is participating in NIH-funded research. The Investigator is required to disclose to the CDT's COIO his/her SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities. The investigator is required to submit to CDT, prior to the expenditure of NIH funds, any reimbursed or sponsored travel related to the Investigator's institutional responsibilities as required in the regulation (see definition of SFI provided in 42 CFR Part 50.603). The Investigator must disclose the SFIs as follows:

- (1) No later than at the time of application for NIH-funded research
- (2) Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI
- (3) At least annually, in accordance with the specific time period prescribed by the Institution, during the period of award

During the period of award, the investigator is required to update all financial disclosures to CDT according to its policy, either on an annual basis or within 30 days of the acquisition or discovery of new SFIs.

Review of Disclosure Forms

CDT's COIO shall review disclosure forms for the possibility that a SFI could be affected by the NIH-funded research; or that the SFI is in an entity whose financial interests could be affected by the research. Through reasonable determination, CDT's COIO will establish that an FCOI exists when an SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Non-compliance

If the failure of the Investigator to comply with CDT's policy has biased the research, CDT will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. Investigators with unresolved conflicts of interest will not be allowed to participate in research at CDT until the conflict is resolved.

CDT agrees to make information on conflicting interests available to HHS and indicate how those interests have been managed, reduced, or eliminated.

If HHS determines that a PHS-funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an investigator with a conflicting interest that was not disclosed or managed, CDT will require the Investigator to disclose the conflicting interest in each public presentation of the results of the research.

A current version of this FCOI shall remain posted on the CDT website. Updates to the policy will be reflected on the CDT website.