

19. Financial Conflict of Interest Policy for Promoting Objectivity in Research

i. Purpose

The purpose of this policy is to conform with 42 CFR, Part 50, Subpart F and 45 CFR, Part 94. The purpose of these regulations is to develop standards to promote objectivity in research and ensure that any research conducted is free from conflicting potential bias due to a financial interest of the Investigator(s). These regulations require all individuals participating in the design, conduct or reporting of Research funded by the Public Health Services (PHS) complete training on financial conflicts, disclosure of personal financial interests that give the appearance of a conflict of interest, could lead to an actual conflict of interest or that may be later established or received that give rise to an appearance or actual conflict of interest.

ii. Applicability

This policy applies to any ITCA, Inc. employee, whether full time or part-time or contractors who is an Investigator, as defined herein involved in PHS funded Research for or on behalf of the ITCA, Inc, either directly or through contract with another Institution, entity, agency or organization and excluding Small Business Innovation Research (SBIR) Program Phase I applications.

iii. Definitions

As stated in 42 CFR, Part 50, Subpart F and 45 CFR, Part 94, as used in this section the following terms have the following meaning:

- a. 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.
- b. FOCOI Report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- c. Financial Interest** means anything of monetary value, whether or not the value is ascertainable.
- d. Institution** means any domestic or foreign, public or private, entity or organization, excluding a Federal agency, that submits a proposal, or that receives PHS research funding.
- e. Institutional Responsibilities** means an Investigator's professional responsibility on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest which may include for example, activities such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- f. Investigator** means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for

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the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators and consultants.

- g. PD/PI** means the Project Director or Principal Investigator of a PHS-funded research project.
- h. PHS (Public Health Service)** means the Public Health Service of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- i. PHS Regulations** means 42 CFR, Part 50, Subpart F and 45 CFR Part 94.
- j. Research** means a systematic investigation 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 and product development and includes any research 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.
- k. Significant Financial Interest** means anything of monetary value, including but not limited to, salary or other payments for services, including, for example consulting fees or honoraria, equity interests, such as stocks or other ownership interests; and intellectual property rights such as patents, copyrights and royalties from such rights. The term specifically excludes: (1) salary, royalties or other remuneration from the applicant institution; (2) any ownership interests in the institution, if the institution is an applicant under the SBIR Program; (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (4) income from service on advisory committees or review panels for public or non-profit entities; (5) an equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than five percent ownership interest in any single entity; or (6) salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

iv. Investigator Training on Policy

The ITCA requires its Investigators to complete training on ITCA policy on financial conflicts of interest, the Investigators obligation to disclose significant financial interests, these regulations and the Investigator's reporting requirements prior to engaging in research grants or sponsored

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funding research and at least every two years or immediately when the following apply:

1. The ITCA amends its policy;
2. The Regulations are amended;
3. An Investigator is new to the ITCA;
4. A determination is made that an Investigator is not in compliance with the disclosure policy.

v. Disclosure Requirements

1. Planned Participation

The ITCA requires Investigators planning to participate in any PHS funded research is required to disclose prior to the time of application, his or her known Significant Financial Interests as well as disclose known Significant Financial Interests of Investigator's spouse and/or dependent children on the forms approved by the ITCA.

2. Annual Disclosure

The ITCA requires Investigators participating in any ongoing PHS funded research disclose on a yearly basis, his or her known Significant Financial Interests as well as disclose known Significant Financial Interests of Investigator's spouse and/or dependent children on the forms provided by the ITCA.

3. Ongoing and Continuing Duty to Disclose

Investigators participating in any ongoing PHS funded research have an ongoing and continuing duty to disclose any new Significant Financial Interests within 30 days of discovering or acquiring, whether through purchase, marriage, inheritance, gift or otherwise, any new Significant Financial Interest.

vi. ITCA Review and Conflict of Interest Management Plan

The ITCA will designate an Official to collect and review Investigator Financial Disclosure Statement(s) and determine whether any disclosed Significant Financial Interest is related and whether a financial conflict of interest exists. If the Official determines a reasonable financial conflict of interest exists, ITCA will adopt a Conflict of Interest Management Plan to properly manage any identified financial conflict of interest.

A Conflict of Interest Management Plan may include the following:

- (1) Public disclosure of the conflict of interest;
- (2) Appointment of an independent monitor to protect the design, conduct and reporting of the research from bias;
- (3) Modification of the research plan to protect the integrity of the research;
- (4) Change or disqualification of individuals involved in any funded research;

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- (5) Reduction or elimination of the conflict of interest;
- (6) Termination of relationships causing the conflict of interest; and
- (7) Any combination of the foregoing as well as any reasonable recommendations made by any partnering agency participating in any funded research.

vii. Failure to Disclose

In the event an Investigator fails to timely disclose an interest that is later determined by the designated ITCA official to be a Significant Financial Interest, ITCA shall complete a review of all of Investigator's activities and the research project to determine whether the research related activities completed during the period of non-disclosure, including the design, conduct and reporting, was biased in any manner.

viii. Monitoring

In the event ITCA adopts a Conflict of Interest Management Plan, ITCA will conduct periodic review to monitor Investigator's compliance with the plan adopted throughout and until completion of the funded research.

ix. Reporting a Conflict of Interest

When ITCA determines a financial conflict of interest exists, whether before or during the research project, ITCA will notify the funding agency and/or the research sponsor, in writing of the conflict of interest within thirty (30) calendar days. The notice will also include the Conflict of Interest Management Plan and/or corrective action taken. The report should include sufficient information to allow the funding agency and/or the research sponsor to understand the nature and extend of any conflict of interest and to review the appropriateness of the Conflict of Interest Management Plan.

x. Remedies

Failure to comply with this policy will be reviewed on a case-by-case basis. Actions for any failure may include but is not limited to the following:

- (1) Probation or Disqualification from participating in future funded research; and
- (2) Personnel action which may include termination.