

3C Institute Financial Conflict of Interest Policy

3-C Institute for Social Development, dba 3C Institute, has adopted the following Conflict of Interest Policy and Statement. Each calendar year, and as new financial interests arise, all key personnel involved in research activities must submit a completed Financial Conflict of Interest (FCOI) Disclosure Statement to the CFO. At the time of hire, and every four years thereafter, each employee involved in research activities will complete conflict of interest training.

An employee shall disclose to 3C Institute any situation in which the employee, spouse, and/or dependent children have a real or potential conflict of interest related to the employee's institutional responsibilities that meets the Significant Financial Interests (SFI) minimum threshold of \$5,000. The employee's supervisor shall determine an appropriate way to manage the conflict of interest and ensure that company business and/or research activities are not improperly influenced or adversely affected. In the event the supervisor concludes there is no reasonable way to manage a conflict of interest, the employee may be prohibited from participating in related company business and/or research activities. In other words, employees have a responsibility to immediately disclose any real or potential conflicts of interest, and the employee's supervisor has a duty to manage the conflicts in the best interests of the company and to ensure objectivity in research.

- a. An employee shall disclose conflicts of interest in writing on the company's Financial Conflict of Interest Disclosure Statement, including a brief description of the nature and extent of the conflict, which shall be submitted for review by the employee's supervisor. This disclosure should be completed at least annually. A new disclosure form should also be completed within thirty (30) days of whenever a new SFI arises or is discovered. The supervisor will review each disclosure and implement a management plan within sixty (60) days.
- b. If the supervisor becomes aware of a conflict of interest that an employee has not disclosed, the supervisor shall discuss the situation with the employee, require that a written disclosure be made as provided in this policy, and manage the conflict. The supervisor will review each disclosure and implement a management plan within sixty (60) days.
- c. The supervisor shall carefully evaluate all circumstances relating to a potential conflict of interest before acting to approve or disapprove the associated activities.

The following are examples of conflicts of interest requiring employee disclosure. These examples are illustrations only and are not meant to be exclusive:

- Employee or immediate family member owns, in whole or in part, a business entity with which the company does or proposes to do business, and the employee is in a decision-making role or otherwise is in a position to influence the company's business decisions regarding the business entity. Business entity examples for which an employee disclosure is required:
 - a. Consulting
 - b. PC or other hardware services
 - c. Programming
 - d. Grant preparation
 - e. Temporary personnel services

f. Office or lab supplies

- Employee holds or assumes an executive, officer, or director position in a for-profit or not-for-profit business or entity engaged in commercial or research activities similar to those in which the company engages.
- Employee participates in consultation activities for a for-profit or not-for-profit business or entity engaged in commercial or research activities similar to those of the company.

Employee Responsibilities

Employees shall not engage in the prohibited activities listed above or in any other activity that their supervisor has prohibited following review of an employee's conflict of interest disclosure.

Employees shall disclose a conflict of interest as described above:

- a. As soon as the employee knows of the conflict, and then annually thereafter for as long as the conflict continues to exist,
- b. In writing on the company's Financial Conflict of Interest Disclosure Statement, and
- c. To the employee's supervisor.

Employees shall avoid any involvement with all related company activities and decisions until the supervisor has evaluated and approved the reported conflict of interest.

If there is any question whatsoever about whether an external activity represents a conflict of interest, then the employee should consult with his or her supervisor for direction. If the employee's supervisor is not available within a reasonable period of time, then the employee should contact the CEO/CFO for direction.

FCOI and PHS-Funded Research

If bias is found with the design, conduct, or reporting of PHS-funded research, this bias will be reported to the funding agency within sixty (60) days. A Mitigation Report will be submitted according to funding agency regulation. The funding agency will also be notified within sixty (60) days if an employee or consultant on a PHS-funded research project fails to comply with this FCOI policy or if a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research. Failure to comply with this FCOI policy can result in disciplinary action depending on the severity of the situation.

FCOI Records

All FCOI-related records will be kept on file in the 3C Business Office for at least three (3) years.

Remedies

In the event that a SFI was not disclosed in a timely manner or previously reviewed, or whenever a FCOI is not identified or managed in a timely manner, the 3C Executive Committee, in conjunction with the employee's supervisor, will complete and document retrospective reviews within 120 days of identification and determination of the non-disclosure. 3C will notify the PHS Awarding Component promptly and submit a report in cases in which bias is found. The report will address the impact of the bias on the research project and the actions 3C has taken, or will take, to eliminate or mitigate the effect of the bias.

In the event the Department of Health and Human Services determines a PHS-funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted or reported by an employee or consultant with a

FCOI that was not managed or reported by the Institution as required by this policy, 3C Institute shall require the individual to:

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

Subrecipient Requirements

Subrecipient organizations and/or institutions must attest to their compliance with 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research” as a part of the 3C Subaward Agreement, which is executed at the start date of all federally-funded project periods. Article 15 of the 3C Institute Subaward Agreement states:

Subrecipient organization/institution certifies that it maintains an active conflict of interest policy that is consistent with the provisions of 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research.” Subrecipient also certifies that, to the best of Institution’s knowledge (1) all financial disclosures have been made related to the activities that may be funded by or through agreement, and required by its conflict of interest policy; and (2) all identified conflicts of interest have or will have been satisfactorily managed, reduced, or eliminated in accordance with subrecipient’s conflict of interest policy prior to the expenditure of any funds under this agreement.

Subrecipient organizations must also report any subsequent FCOI to 3C within sixty (60) days of identification.

Publicly Accessible Information

The 3C FCOI Policy is publically available on the company website at: <http://www.3cisd.com/static/ccisd/uploads/files//fcoi.pdf>. Any and all identified instances of FCOI will be posted at this web address within sixty (60) days of a newly identified FCOI and will remain available for three (3) years. The information to be reported includes the employee’s name, the employee’s title and role with respect to the research project, the name of the entity in which the SFI is held, the nature of the SFI, and the approximate dollar value of the SFIR, 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.

Definitions

- Financial Conflict of Interest (FCOI)* exists when the Institutional designated official(s) reasonably determines that Significant Financial Interest (defined below) could directly and significantly affect the design, conduct, or reporting of federally funded research.
- Institution* refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is the direct and primary recipient of federal grant funds or that submits a proposal for a research contract whether in response to a solicitation from the federal government or otherwise, and is accountable to the federal government for the performance of the project/contract, the appropriate expenditure of grant/contract funds by all parties, and all other obligations of the grantee/awardee, such as compliance with the terms and conditions of NIH grant/contract awards, including FCOI.
- Research* is the systematic investigation designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research and product development. As used in this context, the term includes any activity for which research

funding is available from the federal government through a grant, cooperative agreement, or contract.

- d. *Significant Financial Interest* is defined by the regulation as anything of monetary value, whether or not the value is readily ascertainable, including but not limited to:
- Salary or other payments for services (e.g., consulting fees or honoraria);
 - Equity interests (e.g., stocks, stock options, or other ownership interests);
 - Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Significant Financial Interest does not include:

- Salary, royalties, or other remuneration from the Institution;
 - Any ownership interests in the Institution, if the Institution is an applicant under the SBIR/STTR Programs;
 - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education, or an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institute of higher education.
 - Income from service on advisory committees or review panels for public or nonprofit entities;
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions made in these vehicles.
 - Travel reimbursed or sponsored by sponsored by a federal, state, or local government agency, an Institution of higher education, or an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institute of higher education.
 - An equity interest that when aggregated for the employee and the employee's spouse and dependent children, meets both the following tests: 1) does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value and 2) does not represent more than 5% ownership interest in any single entity; or
 - Salary, royalties, or other payments that when aggregated for the employee and the employee's spouse and dependent children over the next 12 months is not expected to exceed \$5,000.
- e. *Small Business Innovation Research (SBIR)* is an award designed to support projects from small businesses ultimately having commercial viability.
- f. *Small Business Technology Transfer (STTR)* is a program under the Small Business Innovation Research Program designed to foster technological innovations through cooperative efforts between small business and research institutions. The STTR grants are awarded for projects having potential for commercialization.



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I, the undersigned, do hereby affirm the following as of the date indicated:

1. I have completed conflict of interest training within the last four years,
2. I have received a copy of the conflicts of interest policy,
3. I have read and I understand the policy,
4. I agree to comply with the policy, and report any known conflicts immediately.

Printed name of employee

Signature of employee

Affirmation Date

Printed witness name

Signature of witness

Witness Date

Financial Conflict of Interest Disclosure Statement

1. If you or any member of your immediate family (spouse, children, parent, in-laws, or siblings) has a financial interest in a company with which 3-C does or proposes to do business, please indicate the following:
- Yes No I own equity in the company (stock ownership equal to or greater than 5%, Stock Options, Real Estate, or other ownership interest in any amount).
 - Yes No The company holds patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, or siblings).
 - Yes No I or a member of my immediate family hold(s) a position of senior management or directorship with the company.
 - Yes No I am a scientific advisor or consultant to the company and I receive honoraria exceeding \$5,000 annually.

If you answered yes to any of the statements above, how will this conflict of interest be managed?

2. Do you or any member of your immediate family (spouse, children, parent, in-laws, or siblings) hold an executive, officer, or director position in a for-profit or not-for-profit business or entity engaged in commercial or research activities similar to those in which 3-C engages?
- Yes No

If you answered yes to the question above, how will this conflict of interest be managed?

3. Do you or any member of your immediate family (spouse, children, parent, in-laws, or siblings) participate in consultation activities for a for-profit or not-for-profit business or entity engaged in commercial or research activities similar to those in which 3-C ISD engages?
- Yes No

If you answered yes to the question above, how will this conflict of interest be managed?

Printed Name

Signature

Date