

**POLICY FOR MANAGING FINANCIAL CONFLICTS  
OF INTEREST (FCOI) AT STRATATECH CORPORATION**

**Revised Following FCOI 2011 Regulation – 42 CFR Part 50 Subpart F (Grants and Cooperative Agreements) and 45 CFR Part 94 (Responsible Prospective Contractors)**

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## I. INTRODUCTION

### A. POLICY PURPOSE

The United States Public Health Service (PHS) 2011 regulations have unique requirements regarding financial conflict of interest (FCOI) reporting and conflict management. All PHS agencies require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94)” (FCOI Regulations).

The PHS 2011 regulations (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>) amend the 1995 regulations by expanding and adding transparency to investigators’ disclosure of significant financial interests, enhancing regulatory compliance and effective institutional oversight and management of investigators’ financial conflicts of interests, as well as HHS compliance oversight.

United States PHS agencies required to follow the PHS 2011 regulations include the following:

- 1) National Institutes of Health (NIH)
- 2) Centers for Disease Control and Prevention (CDC)
- 3) Health Resources and Services Administration (HRSA)
- 4) Substance Abuse and Mental Health Administration (SAMHSA)
- 5) Agency for Toxic Substances and Disease Registry (ATSDR)
- 6) Indian Health Service (IHS)
- 7) Food and Drug Administration (FDA)
- 8) Agency for Healthcare Research and Quality (AHRQ)

Non-PHS agencies may adopt the PHS FCOI regulations as well, thereby requiring awardee institutions to adhere to these regulations.

Stratatech Corporation (“Company”) must ensure that the integrity of research grants, cooperative agreements, and contracts, and the safety and/or welfare of research subjects are never subordinate to, or compromised by, financial interests or the pursuit of personal gain. The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of the Company and their external constituencies in order to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests. Each investigator is required to disclose a listing of his/her significant financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research purposed for funding by the PHS. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, the Company will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias due to the conflict of interest. This policy statement is intended to satisfy current federal regulations for disclosure with regard to projects funded by the PHS.

### B. SCOPE

This policy is applicable immediately to all PHS-funded program activities at the Company carried out by Company employees, consultants, scientists, trainees, technicians, and other agents or research collaborators (“Company employees”). In addition it applies to non-PHS-funded program activities for

which the sponsor has adopted the PHS 2011 FCOI regulations. The requirements of the FCOI Regulations do not apply to PHS-funded Phase I Small Business Innovation Research Grant (SBIR) or Small Business Technology Transfer Grant (STTR) funding.

## II. DEFINITIONS

A. Financial Conflict of Interest (FCOI) is considered to occur when:

- 1) A Company employee, or a family member of the Company employee, has an existing or potential financial or other material interest that impairs, or appears to impair, the Company employee's independence and objectivity in the execution of his/her responsibilities to and/or for the Company.
- 2) A Company employee receives financial or other material benefit through inappropriate use of knowledge or information confidential to the Company.
- 3) Financial or personal obligations may compromise or present the appearance of compromising an investigator's professional judgment in conducting, reviewing, or reporting on research or non-research-related projects. This may include, but is not limited to, interests in the research/project itself or in the sponsor (including equity holdings, consulting arrangements, or patent rights), or any other incentive which may bias the collection, analysis, and interpretation of data or negatively impact scientific objectivity and integrity.

B. Company Employee is any individual employed on a full- or part-time basis by the Company and is receiving, or will receive, compensation for such employment, including consultants, agents and research collaborators of the Company.

C. Investigator is the principal investigator, co-principal investigators, or any other Company employee responsible for the design, conduct, or reporting of externally funded scientific research activities.

D. Family Member includes the Company employee's spouse or domestic partner, children, or other adults who qualify as dependents under the Internal Revenue Code definitions.

E. Project implies any externally funded activity such as basic, applied, or developmental research, or other activity conducted by Company employees on behalf of the Company.

F. Significant Financial Interest (SFI)

- 1) Publicly Traded Entities – With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 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 or 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.
- 2) Privately Held Entities – With regard to any privately held entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse, domestic

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

- 3) Intellectual Property – With regard to intellectual property rights and interests (e.g., patents and copyrights) a SFI exists upon receipt of income related to such rights and interests.
- 4) Travel Reimbursements – With regard to 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 his or her institutional responsibilities in the 12 months preceding the disclosure; 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 definition of an SFI does not include:** salary, royalties, or other remuneration paid by the Company to the investigator, if the investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company 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 governmental 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, from an institution of higher education as defined at 20 U.S.C. 1001(a), or from an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.

G. Institutional Responsibilities: An investigator’s professional responsibilities on behalf of the institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, and institutional committee memberships.

H. Negative Finding means a determination has been made that no financial conflict of interest exists.

I. Positive Finding means a determination has been made that a financial conflict of interest does exist and, therefore, appropriate administrative action will be required as given under Section III, Part E.

### III. POLICY STATEMENT

#### A. INVESTIGATOR TRAINING

In accord with relevant Federal and State of Wisconsin regulations, the Company is required to manage, eliminate, or reduce any potential FCOI that may be inherent in the personal financial interest of an investigator. The Company, therefore, will be responsible for ensuring that each investigator is informed about:

- 1) The Company’s FCOI Policy
- 2) The investigator’s responsibilities regarding disclosure of significant financial interests relating to the investigator’s institutional responsibilities
- 3) PHS FCOI regulations

In accordance with FCOI regulations, the Company requires each investigator to complete a mandatory training module prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every 4 years thereafter, and immediately when any of the following applies:

- 1) This FCOI Policy or the PHS Financial Disclosure Form are revised in any manner that affects the requirements of the investigators;
- 2) An investigator is newly appointed at the Company;
- 3) The Company finds that an investigator is not in compliance with this FCOI policy or management plan (See Section III, Part E).

## B. INVESTIGATOR DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

The Company requires investigators to disclose to the Company any significant financial interest, including those of his/her family members, which would reasonably appear to be affected by the project being funded by external agencies. The Company will provide an efficient and effective method for soliciting and reviewing timely disclosures from investigators through a written and signed disclosure statement (Disclosure of SFI Form). Investigators are required to provide updated disclosure information no later than the time the respective application is submitted to PHS; at least annually during the period of the award; and within 30 days of discovering or acquiring a new SFI. The Company will review disclosures of SFI(s) of the investigator and those of the investigator's spouse, domestic partner, or dependent child related to an investigator's institutional responsibilities.

## C. IDENTIFICATION OF FINANCIAL CONFLICT OF INTEREST (FCOI)

In conjunction with the administrative review of applications for grants, contracts, or cooperative research agreements, the Director of Research & Development, in conjunction with an Officer of the Company will review each financial disclosure submitted and shall make the determination of whether or not a FCOI exists.

The following examples illustrate when an investigator would be deemed to have an FCOI:

- 1) If the investigator (or investigator's spouse, domestic partner, or dependent child) has a SFI in an entity that could be affected by the research results from a proposed PHS-funded grant or contract based on an analysis of the scope and subject matter of the proposed project;
- 2) If the investigator (or investigator's spouse, domestic partner, or dependent child) has a SFI in an entity that licenses technology from the Company which has resulted in license income and the technology being the subject of a proposed PHS-funded award.

In making a FCOI determination, the Director of Research & Development and an Officer of the Company may consult with all appropriate Company and governmental officials.

If the Director of Research & Development and an Officer of the Company determine that no FCOI exists, the resulting negative finding will be filed in the Company's Human Resources files. No further review is required for negative findings. Positive findings can be appealed (See Section III, Part D) or managed (See Section III, Part E) via a management plan.

#### D. INVESTIGATOR APPEAL OF POSITIVE FINDING

Investigators may appeal a positive finding to the Board of Directors for a review of the FCOI determination reached by an Officer of the Company. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award. In reviewing positive findings, the following principles will be followed:

- 1) Assure adherence to all relevant Company policies;
- 2) Give full considerations to the nature and extent of the financial interests in the relationship of the investigator, and/or the investigator's family members, with the external constituencies;
- 3) Give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation; and
- 4) Consult fully with the investigator and obtain additional information from the investigator, as deemed appropriate to the management of the apparent FCOI.

#### E. MANAGEMENT OF FCOI

Following the determination of a positive finding, or upon receipt of an appeal, the Board of Directors shall make a final determination involving one of the administrative actions:

- 1) Accepting the sponsored project award;
- 2) Not accepting the sponsored project award; or
- 3) Accepting the sponsored project award subject to suitable modifications in the award documentation or in the investigator's, or his/her family's, affiliation with the external constituencies involved.

Reasonable modifications under option 3) above might include one or more of the following actions as part of a FCOI management plan:

- 1) Public disclosure of the identified financial interests;
- 2) Requiring that the data and research results be reviewed by independent reviewers identified by the Chief Scientific Officer (CSO) and the investigator;
- 3) Requiring that the research plan be modified;
- 4) Change in personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- 5) Requiring that the investigator and/or her/his family member(s) divest certain significant financial interests related to the positive finding; or
- 6) Requiring that the investigator and/or his/her family members(s) sever relationships that create the conflict of significant financial interest.

The Company will monitor investigational compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

#### F. REPORTING REQUIREMENTS TO PHS

- 1) Prior to expending any funds under a PHS-funded grant, cooperative agreement, or contract, the Company must report to the applicable funding agency the existence of any FCOI and assure that the Company has implemented a management plan in accordance with the FCOI Regulations and the Conflict of Interest Policy. If the Company identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the Company is not required to submit an FCOI report to the respective agency.

- 2) For any FCOI reported to the respective agency relating to an ongoing PHS-funded research project, the Company will submit an annual report to the applicable funding agency that conforms to the requirements of the FCOI Regulations for the duration of the research project in the time and manner specified by the applicable funding agency.
- 3) For any SFI that the Company identifies as being an FCOI subsequent to the Company's initial FCOI report under the award, the report will be made to the applicable funding agency and a management plan shall be implemented, at least on an interim basis, within 60 days of that identification. If, for whatever reason, the FCOI is one that was not made in a timely manner to the applicable funding agency, the Company will conduct a retrospective review of the investigator's activities and the research project.
- 4) All reporting shall include, at least, the items enumerated under the FCOI Regulations.

## G. COMPLIANCE

If an investigator fails to comply with this FCOI Policy or management plan and the noncompliance appears to have biased the design, conduct, or reporting of the PHS-funded research, the Company, as required under the FCOI Regulations, shall promptly notify the agency of the corrective actions to be taken. The Company shall ensure compliance with the requirements for retrospective review and prepare a mitigation report within 120 days of the determination of noncompliance. If needed, this report will be submitted to the applicable funding agency as required under the FCOI Regulations.

For clinical research projects supported by PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the Company must require the investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts, and oral presentations) of the results of the research and to request an addendum to previously published presentations.

All persons subject to this FCOI Policy are expected to comply with it fully and promptly. If an investigator has violated this FCOI Policy, for example, by failure to disclose an SFI, the Company may take disciplinary or other appropriate action. Intentional disregard for this policy, including non-adherence to the agreed upon management plan, shall constitute serious misconduct and may be the basis for further administrative or legal inquiry.

## H. SUBRECIPIENT REQUIREMENTS

All proposed subrecipients of funds under the Company PHS-funded research shall have an FCOI Policy that conforms to the requirements of the FCOI Regulations. With respect to these subrecipients, subcontractors, and collaborators, the Company must require these entities to enter into a written agreement and make a certification to the Company at the time of award that its FCOI Policy complies with the FCOI Regulations. The written agreement shall include all of the terms required under the FCOI Regulations.

The Company will report to the PHS funding agency any FCOI which is identified by any subrecipient, subcontractor, or collaborator to the Company in the manner required under the FCOI

Regulations, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

## I. POLICY AND FCOI DISCLOSURE PROCEDURES

The Company shall ensure public accessibility of the Company's FCOI policy on a publicly accessible website. If a publicly accessible website is not available, for whatever reason, and only in this case, the Company must make the FCOI policy available within 5 business days of a request. If presence on a publicly accessible website is then acquired, the Company must post the FCOI policy within 30 days.

Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the Company shall ensure public accessibility of information about the FCOI, via a public website or written response to any requestor within 5 business days of a request. The information shall consist of the information required to be provided under the FCOI Regulations, including:

- 1) Investigator's name
- 2) Grant/Contract Number
- 3) Project Director/Principal Investigator
- 4) Investigator with FCOI
- 5) Investigator's (with FCOI) title and role with respect to the research project
- 6) Name of entity in which the SFI is held
- 7) Nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.); and
- 8) Approximate dollar value of the SFI (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.
- 9) A description how the financial interest relates to PHS-funded research and the basis for the FCOI determination.
- 10) How the FCOI is being managed, reduced, or eliminated.

## J. MAINTENANCE OF RECORDS

The Company is required pursuant to the FCOI Regulations to maintain all Disclosure of SFI Forms and all related records of actions taken by the Company with respect to disclosures of financial interests for a period of 3 years from the date of submission of the final expenditures report to PHS or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

## III. BOARD OF DIRECTORS ADMINISTRATIVE PREROGATIVE

During the course of any inquiry or investigation, the Board of Directors shall have the prerogative to take interim administrative actions, as appropriate, to protect external funds and insure that the purposes of the external financial assistance are protected.



## SCREENING FORM FOR IDENTIFYING POTENTIAL FINANCIAL CONFLICT OF INTEREST (FCOI) (Attachment A)

Name: \_\_\_\_\_ Title: \_\_\_\_\_

1. Do you have a significant financial interest\* in a commercial organization (other than Stratatech Corporation) that is directly related to, or would be affected by, your research, or directly relates to a business decision you are participating in? Yes\_\_\_\_ No\_\_\_\_

\* For this purpose, see definition of “Significant Financial Interest” in Stratatech’s FCOI Policy.

2. Do you have some involvement or financial interest that is, or could be perceived to be, in conflict with the completion of your duties at Stratatech Corporation? Yes\_\_\_\_ No\_\_\_\_

3. Do you, or a member of your family, serve as a director, trustee, officer, or other key employee in a for-profit corporation, partnership, business, or other entity in a field of your research or in a company that does business with Stratatech Corporation? Yes\_\_\_\_ No\_\_\_\_

4. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity in a field of your research or in a company that does business with Stratatech Corporation? Yes\_\_\_\_ No\_\_\_\_

5. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity in a field of your research or in a company that does business with Stratatech Corporation? Yes\_\_\_\_ No\_\_\_\_

6. Have you or a member of your family received compensation for activities such as travel expenses, consulting, expert witness, advisory board membership, and the like from an entity in a field of your research or in a company that does business with Stratatech Corporation? Yes\_\_\_\_ No\_\_\_\_

7. Do you or any member of your family have any relationships, commitments, or activities that might, in your good faith judgment, present or appear to present a conflict of interest with your research activities? Yes\_\_\_\_ No\_\_\_\_

If you answer yes to any of the above questions, you will be asked to disclose in further detail any Significant Financial Interest.

**Affirmation**

In signing this form, I affirm to the following:

- 1) The above information is true and accurate. If at any time during my employment any of the above answers are no longer accurate, I will complete a new screening form detailing the change.
- 2) I have read and understand Stratatech Corporation’s Policy for Managing Financial Conflicts of Interest.
- 3) I have completed the online FCOI tutorial (link below) provided by the NIH and understand my responsibilities related to identifying and managing FCOI at Stratatech Corporation.  
<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Stratatech Corporation Officer

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Negative Findings: \_\_\_\_\_ Positive Findings: \_\_\_\_\_



Stratatech Corporation
505 S. Rosa Road, Suite 169
Madison, WI 53719
608-441-2750
fax - 608-441-2757
www.stratatechcorp.com

DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS FORM

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Grant Proposal Title: \_\_\_\_\_

Intended Government Funding Agency: \_\_\_\_\_

Name of Constituent Organization / Institution in which you claim a Significant Financial Interest:

Name

Address

City State Zip

1. Describe your significant financial interest in the organization (other than Stratatech Corporation) that is directly related to your research interest (or would be affected by your research) or directly relates to a business decision you are participating in:

Four horizontal lines for text entry.

2. Describe your involvement or financial interest that is, or could be perceived to be, in conflict with the execution of your duties for Stratatech Corporation:

Four horizontal lines for text entry.