

## 1. Purpose

External sponsorship of research can result in the development of complex relationships between researchers and the external sponsors who support specific programs. To assure that our research is conducted with the highest integrity and in response to regulations issued by the Public Health Service (PHS) and National Science Foundation (NSF) Rules on Objectivity in Research (Federal Register 42 CFR Part 50 subpart F), Mercator MedSystems, Inc. (“Mercator”) has developed this policy on Financial Conflict of Interest (FCOI).

The purpose of this policy (the “Policy”) is to promote objectivity in research, to identify and eliminate or manage FCOI, to promote and enforce Investigator compliance with the Regulation, to manage FCOI and provide initial and ongoing FCOI reports, to make FCOI and SFI information available to PHS upon request, and to satisfy current Federal regulations for disclosure.

## 2. Scope

This policy is immediately applicable to all sponsored program activity at Mercator. These procedures will be followed whenever Mercator submits a request for funding from any external agency, whether it is the PHS, the NSF, or other Federal agency.

This regulation does not apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs Phase I applications/awards.

## 3. Investigator Training Requirements

Each Investigator must complete Mercator FCOI training:

- a) prior to engaging in research related to any PHS-funded grant,
- b) at least every 4 years, and
- c) immediately, if
  - i) Mercator revises its FCOI policy that affects requirements of Investigators,
  - ii) an Investigator is new to Mercator, or
  - iii) an Investigator is found by Mercator to not be in compliance with the Policy or an FCOI Management Plan.

The training shall inform the Investigator of this policy, the Investigator’s responsibilities regarding disclosure of his/her SFI, and the federal regulations pertaining to FCOI.

Training materials and certification can be found at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>.

## 4. Investigator Disclosures

Each Investigator must disclose or update all Significant Financial Interests (SFI) no later than:

- a) at the time of application for PHS-funded research,
- b) at least annually during the period of an award,
- c) within 30 days of discovering or acquiring a new SFI, or
- d) when the Investigator becomes active in any PHS-funded research project.

Disclosure is accomplished through the completion of a “Significant Financial Interest Disclosure Form” (Attachment A). All SFI disclosure forms are confidential and will be reviewed by the FCOI Committee to determine the existence of or potential for any FCOI. If FCOI is present, the FCOI shall be properly managed or eliminated and the Investigator must agree in writing to a FCOI Management Plan, if one is implemented, before any related contract, grant, sponsored protect, or any other transaction is executed, any relationship is initiated, or any action is taken that could be influenced by the SFI.

## 5. Sub-Recipient Disclosures

If research is done on behalf of the Company through institutional sub-recipients, the Company will incorporate, as part of a written agreement with the sub-recipient, terms that establish whether the Company’s or the sub-recipient’s FCOI policy will apply to the sub-recipient’s Investigators. Additionally, the written agreement should address the time frames within which the sub-recipient must provide either (i) FCOI information necessary to ensure that the Company is able to meet its FCOI reporting obligations to the PHS awarding agency, or (ii) financial disclosure information to enable the Company to comply timely with its review, management, and reporting obligations under the Regulation. If a sub-recipient defers to the Company’s FCOI Policy, the individuals at the sub-recipient involved in the design, conduct, or reporting of the research are considered Investigators as defined in the Company FCOI Policy. If a sub-recipient’s policy applies, the sub-recipient must certify that its policy complies with the Regulation.

## 6. Definitions

For purposes of this policy the following definitions are provided:

Dependent Child: a natural or adopted child of the Investigator who is under the age of 18 years.

Entity: any domestic or foreign, public or private, for-profit or not for-profit, business, organization, association; including but not limited to a sole proprietorship, partnership, corporation, or limited liability company.

Equity Interest: to ownership interest in an Entity, including by not limited to, stock or stock options or partnership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Conflict of Interest Committee: the committee established by Mercator to assist in implementing and enforcing this policy. Responsibilities of the committee shall include:

- a) Review all SFI disclosures,
- b) Determine FCOI,
- c) Develop and implement FCOI Management Plans,
- d) Review noncompliance issues, and
- e) Provide initial and annual (i.e., ongoing) FCOI reports to the NIH through the eRA Commons FCOI Module, as required.

Financial Conflict of Interest (FCOI) Management Plan: the action(s) taken to address an FCOI, which may include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be objective and free from bias.

Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.

Immediate Family: Investigator's spouse and dependent children or other adults who qualify as dependents under the Internal Revenue Code definitions.

Institution: any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is the direct or primary recipient of NIH/PHS Agency federal grants or funds or that submits an application/proposal for a federally funded research grant.

Investigator: the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed for funding with federal funds, which may include, for example, collaborators or consultants.

Manage: taking action to address FCOI, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Research: a systematic investigation, study or experiment 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 (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest (SFI):

- a) A financial interest consisting of one or more of the following interests of the Investigator (or her/his 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.
  - b) 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.
  - c) 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.

## **7. Procedures for Determining and Addressing Conflict**

No awarded PHS funds can be expended until all FCOI related to a grant have been eliminated, reduced, or managed.

The FCOI Committee oversees and manages the implementation of this Policy. The FCOI Committee will review each SFI Disclosure Form to determine: (a) whether reported SFI reasonably appears to be related to the Investigator's PHS-funded research and/or other Institutional Responsibilities, and, (b) if related, whether the SFI could directly and significantly affect the design, conduct, or reporting of the research. If the answer to both (a) and (b) is "Yes", an FCOI may be found to exist.

If the Committee determines that the Investigator has an FCOI, the Committee will work with the Investigator on a management plan to eliminate, reduce, or manage the conflict. Management plan elements may include, but are not limited to, requiring the Investigator to disclose the potential FCOI to laboratory or study team members working on the research, to research participants, and/or to publishing journals; establishing independent review of research data; and/or requiring the Investigator to relinquish the SFI. The Company will monitor the Investigator compliance with each imposed management plan on an ongoing basis until completion of the PHS-funded research project.

To the extent that a new or previously unreported SFI is disclosed during the course of PHS-funded research (e.g., an Investigator who is new to the research project discloses SFI or a previously named Investigator discloses new or previously unreported SFI), the Committee will, within 60 days from the date of the disclosure, determine whether an FCOI exists, and, if so, will implement a plan to eliminate, reduce, or manage the conflict.

If an FCOI is not identified or managed as required, due to (i) a failure by an Investigator to timely disclose SFI that is later determined by the Committee to constitute an FCOI, (ii) the Company's failure to review or manage such an FCOI, or (iii) an Investigator's failure to comply with an FCOI management plan, the Company will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and PHS-funded research to determine whether the design, conduct, or reporting of the research has been affected by bias. The Company will document the retrospective review, including, at a minimum, (i) the project number and title, (ii) the Investigator's name and the entity creating the FCOI, (iii), the Principal Director/Principal Investigator contact information, (iv) the reason(s) for the review, (v) the detailed methodology used for the review, and (vi) the findings and conclusions. The Company will notify the PHS awarding agency of any bias found in the PHS-funded research and will submit a mitigation report that addresses the impact of the bias on the research project and the Company's plan to eliminate or mitigate the effect of the bias.

Mercator will maintain the confidentiality of the disclosure statements except as required by federal law or agency award terms. In no case will a disclosure statement be released to a federal agency without prior notification to the affected individual.

## **8. Roles and Responsibilities**

Mercator Responsibilities:

- a) Comply with federal regulations by developing, communicating, and enforcing a written FCOI policy.
- b) Inform each Investigator of Mercator's FCOI Policy and of the Investigator's responsibilities regarding disclosure of SFI.
- c) Require each Investigator to complete training regarding SFI and Mercator's FCOI Policy prior to engaging in research, at least annually, and immediately when any of the following circumstances apply:
  - i) Mercator revises its FCOI Policy or procedures in any manner that affects the requirements of Investigators;
  - ii) An Investigator is new to Mercator; or
  - iii) Mercator finds that an Investigator is not in compliance with the Mercator's FCOI Policy or Management Plan.
- d) Take reasonable steps to ensure that any subcontractor complies with federal FCOI regulations by incorporating as part of the written agreement that the subcontractor possesses a written FCOI policy that is compliant with all federal regulations and that subcontractor provides Mercator with a written copy (and any subsequent revisions) of its FCOI policy within 15 days of the written agreement or revisions to its FCOI policy.

- e) Require each Investigator who is planning to participate in federally funded research to disclose SFI and those of the Investigator's immediate family no later than submission of the research proposal, at least annually, and within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, inheritance) of a new SFI.
- f) Use federal regulations as a guideline for determining whether an Investigator's SFI is related to federally funded research and, if so, whether the SFI is a FCOI.
- g) Take actions as necessary to manage FCOI, including the FCOI of subcontractors, through the development and implementation of a FCOI Management Plan, and, if necessary, a retrospective review and mitigation report.
- h) Provide initial and annual (i.e., ongoing) FCOI reports to the NIH through the eRA Commons FCOI Module, as required; prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- i) Maintain records of all documentation and disclosure for a minimum of 3 years from the date of any applicable final expenditures report is submitted to the PHS (NIH).

Investigator Responsibilities:

- a) Comply with this policy.
- b) Make disclosures as required by this policy.
- c) Work with the FCOI Committee to determine if there is an FCOI.
- d) Assist in developing and complying with any FCOI Management Plan.

**9. Noncompliance/Failure to Disclose or to Abide by FCOI Management Plan**

Any suspected non-compliance with this policy shall be handled by the FCOI Committee in accordance with applicable regulatory requirements. Based on the findings and recommendations of the FCOI Committee, Mercator is authorized to stop research or hold research funding in order to ensure compliance with this policy, an FCOI Management Plan, and/or applicable federal FCOI regulations.

**1. Please provide your contact information:**

Name:	
Title of Project:	
Role on Project:	

**2. On the table below, check “Yes” or “No” for each category of financial interest listed. You must also check “Yes” if a financial interest is held by your spouse or your dependent children. Only indicate significant financial interests that are directly related to the work that you will be performing on the project. Use additional pages if needed.**

Nature of the Significant Financial or Business Interest	Yes	No	If Yes, Name of Entity/Entities	Value (\$ US)
Equity in, and/or compensation in the past 12 months from, a publicly traded entity, that when aggregated exceeds \$5,000.				
Compensation in the past 12 months from a non-publicly traded entity exceeding \$5,000.				
Any amount of equity in a non-publicly traded entity exceeding \$5,000 in the past 12 months.				
Incomes from intellectual property exceeding \$5,000 in the past 12 months.				
Any other intellectual property rights or interest (regardless of income).				
Sponsored or reimbursed travel, regardless of cost or amount*				

**\*If you answered “Yes” to travel, please indicate the following for each trip. Use additional pages if needed.**

Entity:	
Destination:	
Duration:	
Purpose:	
Value:	

**3. Is there any potential that the work you perform for Mercator MedSystems could affect the monetary value of the significant financial interest being disclosed? Please provide a detailed answer.**

**4. I certify that I have read and understood the Mercator Financial Conflict of Interest Policy.**

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

**I certify that all information is complete and accurate to the best of my knowledge:**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date