

Certified

- + ISO 13485:2003
- + ISO 14971:2007
- + Women-Owned

Title: Financial Conflict of Interest

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 July 11, 1995; revised regulation 2011), Actuated Medical, Inc. (AMI) has developed this policy on Financial Conflict of Interest (FCOI). The intent of this policy is to promote objectivity in research, to identify and eliminate or manage any possible threat to the integrity of the research conducted by AMI, and to satisfy current Federal regulations for disclosure.

Scope:

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

Policy Statement:

All Investigators must disclose all Significant Financial Interests (SFI) prior to the submission of a research proposal to any federal agency, annually, and within thirty (30) days of the discovery or acquisition (e.g., through purchase, marriage, or inheritance) of a new SFI to the Director Medical Affairs who reports to the President and who is member of the Financial Conflicts of Interest Committee (FCOIC). Disclosure is accomplished through the completion of a "Significant Financial Interest Form" (Attachment A). All SFI disclosure forms are confidential and will be reviewed by the FCOIC to determine the existence of or potential for any FCOI. If a 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 project, or any other transaction is executed, any relationship is initiated, or any action is taken that could be influenced by the SFI.

In addition, all subcontract awards will include a requirement that the subcontract award recipient has a FCOI policy that is compliance with all federal regulations and that the subcontract award recipient will immediately report any FCOI to AMI.

All Investigators must complete FCOI training identified by AMI at least every four (4) years or immediately upon the occurrence of one of the following circumstances: 1) when AMI makes revisions to this policy that impacts an Investigator's responsibility under this policy, 2) when an Investigator is a new hirer to AMI, and 3) when AMI finds that an Investigator is not in compliance with this policy or with his/her 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.

**Definitions:**

For purposes of this policy the following definitions are provided:

- A.** Dependent Child(ren) – refers to a natural or adopted child of the Investigator who is under the age of 18 years.
- B.** Entity – refers to 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.
- C.** Equity Interest – refers to ownership interest in an Entity, including but 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.
- D.** Financial Conflict of Interest (FCOI) – refers to a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
- E.** Financial Conflict of Interest Committee (FCOIC) – refers to the committee established by AMI to assist the Director Medical Affairs in implementing and enforcing this policy. Members shall include the Director Medical Affairs, Business Manager, Director Quality Assurance, Project Manager, and others as appointed by the President. The FCOIC shall meet on a quarterly basis and as needed. Responsibilities of the FCOIC shall include:
 - + Review all SFI disclosures.
 - + Determine FCOI.
 - + Develop and implement FCOI Management Plans.
 - + Review noncompliance issues.
- F.** Financial Conflict of Interest (FCOI) Management Plan – refers to 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.
- G.** Financial Interest – refers to anything of monetary value, whether or not the value is readily ascertainable.
- H.** Immediate Family – refers to Investigator’s spouse and dependent children or other adults who qualify as dependents under the Internal Revenue Code definitions.
- I.** Institution – refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is the direct or primary recipient of federal grants or funds or that submits an application/proposal for a federally funded research grant.
- J.** Investigator – refers to 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.
- K.** Manage – refers to 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.
- L.** Research – refers to 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 and product development.

M. Significant Financial Interest (SFI) is defined as:

- + A financial interest consisting of one or more of the following interests of the Investigator and the Investigator's immediate family that reasonably appears to be related to the Investigator's institutional responsibilities:
 - + With regard to any publicly traded entity, a SFI 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.
 - + With regard to any non-publicly traded entity, a SFI 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 immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest).
 - + 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.

N. Significant Financial Interest does not include:

- + Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution.
- + Income from seminar, lectures, or teaching engagements sponsored by federal, state, or local government agency, an institution of higher learning, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher learning.
- + Incomes from service on advisory committees or review panels for a federal, state, or local government agency, institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher learning.

**Procedure:**

1. Investigators must complete a SFI form 1) prior to the submission of an application for funding, 2) at least annually, 3) within thirty (30) days of the discovery or acquisition (through purchase, marriage, or inheritance) of a new SFI, and 4) upon hire.
2. For each new grant submitted, the FCOIC will identify the subcontractors and confirm that they have FCOI assurance in their agreements. If language is not in the Master Agreement, an Agreement Addendum will be completed adding the appropriate language. If new subcontractors are added, the FCOIC will ensure FCOI language is included in the contract. When new grants are submitted a list of participants and subcontractors will be kept in the FCOI binder.
3. The FCOIC will review all SFI forms and evaluate whether they contain any FCOI.
4. If no conflict of FCOI is found, the SFI form will be filed in the SFI binder. For negative findings, no further review is required.
5. If a FCOI is identified, the FCOIC will work with the Investigator to prepare a FCOI Management Plan that will reduce, minimize or eliminate the conflict of interest. The FCOI Management Plan must be approved by the FCOIC and signed by the Investigator before any federal grant expenditures.
6. If the FCOIC is unable to satisfactorily manage a FCOI, the FCOIC will notify the appropriate official at the funding agency as required by agency regulations.
7. In the event circumstances change regarding an Investigator's SFI while an Investigator is engaged in a sponsored project, the Investigator must notify AMI and complete a new SFI form within thirty (30) days of discovery. The new SFI form will undergo the same review process as all SFI forms.
8. AMI 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.

Roles and Responsibilities:

Institution's Responsibilities:

- A. Comply with federal regulations by developing, communicating, and enforcing a written FCOI policy.
- B. Inform each Investigator of AMI's FCOI Policy and of the Investigator's responsibilities regarding disclosure of SFI.
- C. Require each Investigator to complete training regarding SFI and AMI's FCOI Policy prior to engaging in research, at least every four (4) years, and immediately when any of the following circumstances apply:
 - + The AMI revises its FCOI Policy or procedures in any manner that affects the requirements of Investigators.
 - + An Investigator is new to AMI.
 - + AMI finds that an Investigator is not in compliance with the AMI's FCOI Policy or Management Plan.
- D. Take reasonable step 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 AMI with a written copy (and any subsequent revisions) of its FCOI Policy within fifteen (15) days of the written agreement or revisions to its FCOI Policy.

- E. Designate the FCOIC to solicit and review SFI forms from each Investigator who is planning to participate in or is participating in federally funded research.
- F. 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.
- G. 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.
- H. 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.
- I. Provide initial and ongoing FCOI reports as required under federal regulations.
- J. Maintain records of all documentation and disclosure for a minimum of three (3) years.

Investigator Responsibilities:

- A. Comply with this policy.
- B. Make disclosures are required by this policy.
- C. Work with the FCOIC to determine if there is a FCOI.
- D. Assist in developing and comply with a FCOI Management Plan.

Noncompliance/Failure to Disclosure or to Abide by FCOI Management Plan

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