

Uncontrolled if Printed

Research, Sponsored Programs, and Innovation Financial Conflict of Interest in Research Policy

Author:	<u>Office of Research Administration</u>
Executive Sponsor:	<u>Vice President of Research, Sponsored Programs & Innovation</u>
Gate Keeper:	<u>Coordinator, Research Administration</u>

Uncontrolled if Printed

1.0 Purpose:

1.1 The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies
- USDA sections 2, 3, and 8 of 2 CFR Part 422

2.0 Scope:

2.1 This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research. Specific guidance and requirements regarding Public Health Service (PHS), USDA, and NSF funded research at Mitotherapeutix are noted in this policy in Section 5.11.

This policy does not apply to applications and awards supported under the Small Business Innovation Research Phase I Program or the Small Business Technology Transfer Phase I program.

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should sponsored project funds be subcontracted by Mitotherapeutix to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

3.0 Definitions:

- 3.1 **Research Official means** the Mitotherapeutix official responsible for the implementation of this policy, including the solicitation and initial review of disclosures of significant financial interest from research Investigators.
- 3.2 **Conflict of Interest Management Plan means** the written plan developed to manage conflicts by mitigating, reducing, or eliminating Financial Conflicts of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.
- 3.3 **Entity means** any domestic or foreign, public, or private, entity or organization (excluding a Federal agency) from which an Investigator (and/or the Investigator's spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.
- 3.4 **Financial Interest means** anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children even if the value is not readily ascertainable.

Uncontrolled if Printed

- 3.5 **Financial Conflict of Interest** means a Significant Financial Interest related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.
- 3.6 **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal Agency) that is applying for, or receives, PHS or NSF research funding.
- 3.7 **Institutional Official** means the individual who is legally authorized to act for the institution, and on behalf of the institution.
- 3.8 **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of Mitotherapeutix including, but not limited to, activities such as research, research consultation, teaching, professional/clinical practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal Care and Use Committees or Data and Safety Monitoring Boards, etc.
- 3.9 **Investigator** means the project director/principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are subcontractors, collaborators or consultants. At Mitotherapeutix this definition includes, but is not limited to, the following roles: Principal investigator, co-investigators, research coordinators, research associates, collaborators and consultants, and may include research assistants and students as identified by the PD/PI depending on their specific roles and responsibilities.
- 3.10 **Management** means actions taken to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, and to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.11 **PD/PI** means the project director or principal investigator of a research project.
- 3.12 **Public Health Service (PHS) Awarding Component** means the organizational unit of the PHS that funds the research (e.g., National Institutes of Health).
- 3.13 **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research through which an investigator collects data through intervention or interaction with animal or human subjects, or from identifiable private information. The term encompasses basic and applied research and product development. The term also includes any such activity for which research funding is available from a US government Awarding Component through a grant or cooperative agreement.
- 3.14 **Senior/Key Personnel** means the Project Director/Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS, NSF, or USDA by the Institution under this subpart.
- 3.15 **Significant Financial Interest (SFI)** means
1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. For 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 the 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 interests includes any

Uncontrolled if Printed

stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- b. 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 (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. For PHS-funded investigators, any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.
 3. The term *significant financial interest* **does not include** the following types of financial interests:
 - a. Salary, royalties, or other remuneration paid by Mitotherapeutix to the Investigator if the Investigator is currently employed or otherwise appointed by Mitotherapeutix, including intellectual property rights assigned to Mitotherapeutix and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, where the Investigator does not directly control the investment decisions made in these vehicles.
 - b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- 3.16 **Small Business Innovation Research (SBIR) Program** - the extramural research program for small businesses established by the awarding components of certain Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public law 102-564.

Uncontrolled if Printed**4.0 Policy**

Each year an investigator who conducts research through the Mitotherapeutix Clinical Research Center (CRC) must disclose via the electronic system all significant financial interests (SFIs) that are relevant to an investigator's institutional research responsibilities or within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has been eliminated.

Investigators are required to complete the annual disclosure form even if they have no financial interest to report. Transactional disclosure by the PI is also required at the time a research proposal is submitted to Sponsored Programs to ensure compliance with federal disclosure and management requirements.

5.0 Procedure**5.1 Investigator Responsibilities****5.1.1 Investigators are responsible for:**

- Disclosing all significant financial interests
- Providing updates to disclosed information as needed
- If acting as the PI/PD, providing a list of individuals who meet the definition of "investigator" (see 3.9) within the required disclosure timeline
- Completing all required training and education
- Completing the annual disclosure form even if they have no financial interests to report.
- Ensuring that an updated FCOI in Research Disclosure is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) approval for any new research proposals.

5.2 Financial Conflicts of Interest

A financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research. Examples include, but are not limited to, the following:

- 5.2.1 Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity that has an interest in the investigator's Mitotherapeutix-based research;
- 5.2.2 Investigator (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research.
- 5.2.3 Investigator (and/or an investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research.

Uncontrolled if Printed

This policy addresses individual financial conflicts of interest; however, Mitotherapeutix may also have conflicts of interest in research whenever the financial interests of Mitotherapeutix, or of a Mitotherapeutix official acting within his or her authority on behalf of Mitotherapeutix, might affect—or reasonably appear to affect—Mitotherapeutix processes for the conduct, review, or oversight of research. If institutional conflicts of interest are identified via the process described below, they will normally be addressed in a manner that is consistent with this policy.

5.3 Review of FCOIs

The designated Research Administration staff member/consultant (Designee) conducts an initial review of all disclosures. If necessary, the Designee obtains additional information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. The Designee then formally identifies cases that require further review and refers such cases to the Research, Sponsored Programs and Innovation Compliance Committee (RCC).

The RCC will review the collected information in accordance with its Charter to determine whether a financial conflict of interest exists by considering the following:

- 5.3.1 Impact on integrity of research data;
- 5.3.2 Risks to rights and safety of animal and/or human research subjects;
- 5.3.3 Risks to the rights of students and trainees participating in research; and
- 5.3.4 Appearance of conflict of interest.

If a financial conflict of interest is identified, the RCC will determine whether the research can be undertaken with appropriate management.

5.4 Management of FCOIs

For cases that require management, a Management Plan will be developed by the Designee and RCC. The Management Plan will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include:

- 5.4.1 Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate;
- 5.4.2 Disclosure of significant financial interests directly to subjects involved in human research;
- 5.4.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- 5.4.4 Modification of research plan;
- 5.4.5 Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- 5.4.6 Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- 5.4.7 Severance of relationships that create the actual or potential conflict of interest;
- 5.4.8 If it proves impossible to reach an acceptable Management Plan, funds will be returned to

Uncontrolled if Printed

the sponsor.

A draft Management Plan will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the final RCC-approved plan to acknowledge their agreement to comply.

If the Institution identifies a SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim management plan will be implemented when necessary.

5.5 Monitoring

Investigator compliance with Management Plans will be monitored by Mitotherapeutix officials. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

5.6 Research Involving Vulnerable Populations

Special consideration and scrutiny must be given to protect human subjects in research. Investigators with an identified financial conflict of interest or a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research shall not ordinarily participate in any research involving human subjects. This presumption against the participation in human subjects' research by financially interested individuals may be rebutted by compelling circumstances. Compelling justification may include factors such as unique investigator expertise, unique institutional resources, unique access to patient populations, nature of the science, level of risk to human subjects and the degree to which the financial conflict of interest and the research are related.

The compelling justification and the degree of risk to human subjects must be presented and reviewed by the Research Official, in collaboration with the Research Compliance Committee. If compelling circumstances justify a waiver of this policy, the research will be subject to the development and implementation of a management plan to ensure the safety of human subjects and the integrity of the research. The IRB must review the research with consideration given to the requirements of the management plan developed by the Research Compliance Committee. The IRB may require additional safeguards to be implemented but may not determine less stringent financial conflict of interest management requirements.

5.7 Appeals

Investigators may appeal Research Compliance Committee decisions in writing within 15 days of receipt of the finalized management plan or other decision of the committee. The written appeal should include details regarding circumstances which support the request for a proposed revision to a committee decision. An Appeals Committee will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Appeals Committee will be convened to review the SFI information, the Management and Monitoring Plan, and previous meeting minutes to make decisions. The Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 60 days from the date

Uncontrolled if Printed

requested by the Investigator. The decision of the Appeals Committee is final and binding.

5.8 Confidentiality

Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel (see Section 5.11.4).

5.9 Enforcement

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or Mitotherapeutix.

5.10 Policy Revision

Mitotherapeutix may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The Research Compliance Committee will have five business days to review and comment on any proposed revisions.

Mitotherapeutix's Vice President, Research or Chief Scientific Officer is responsible for granting final approval. He/she will review all proposed revisions, in collaboration with his/her staff, and will consider the committee's feedback during the review process. When necessary, procedures will be developed or modified to implement this policy.

5.11 Additional Requirements

The following **additional** requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.

5.11.1 Reporting

Mitotherapeutix will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:

Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI.

Mitotherapeutix will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- Grant/Contract Number
- PD/PI

Uncontrolled if Printed

- Name of Investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
- Value of the financial interest 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
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Key elements of the Management Plan

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI
- Changes to the Management Plan
- Justification if FCOI no longer exists

5.11.2 Subrecipients

For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, Mitotherapeutix will require a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding component.

Subrecipients who do not have such a conflict of interest policy will be required to follow the Mitotherapeutix FCOI in Research policy. A subrecipient's failure to promptly comply with the Mitotherapeutix policy will be considered grounds for immediate termination by Mitotherapeutix of any applicable subcontract or subaward. The written agreement terms required by Mitotherapeutix will contain a provision that subrecipients will report to Mitotherapeutix as the awardee Institution, any identified FCOI in sufficient time to allow Mitotherapeutix to report and manage the FCOI to meet the reporting obligations described above.

5.11.3 Travel Disclosure

PHS-funded Investigators must disclose the occurrence of reimbursable or sponsored travel related to their institutional responsibilities, **regardless of the value**. At a minimum the travel disclosure must include:

- Purpose of the trip
- Identity of the sponsor/organizer

Uncontrolled if Printed

- Destination
- Length
- Monetary value, if known

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- 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

Travel disclosures will be reviewed by the Research Official and be referred to the Research Compliance Committee as appropriate, to determine if the travel represents a FCOI with PHS-funded research. Additional information may be requested at the time of review. Disclosure of travel must occur no more than 30 days after the last day of the trip.

5.11.4 Public Accessibility

This policy is to be posted on the Mitotherapeutix public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via **an email** response within five business days from when the Research Official receives the request. This information may be requested by calling **Mitotherapeutix at** or emailing

The written response will include:

- Senior/key personnel name
- Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will remain available for three years from the date the information was most recently updated.

5.11.5 Training Requirements

PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

- This policy changes in a manner that affects Investigator requirements

Uncontrolled if Printed

- An Investigator is new to Mitotherapeutix and will be working on PHS- funded research
- An Investigator is found to be noncompliant with this policy or their approved Management Plan

5.11.6 Investigator/Institutional Non-Compliance

If an SFI is not disclosed or reviewed in a timely manner, Mitotherapeutix will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether a FCOI exists, and if so:

- Implement a Management Plan for ongoing research, at a minimum implement an interim Management Plan
- Complete a retrospective review of Investigator's activities and the PHS-funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
- If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report

If the retrospective review finds that the Investigator knew or should have known about the FCOI related to his/her institutional responsibilities, but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report may be pulled from the Investigator's Indirect Cost Allocation portion, the Investigator's Department, or directly billed to the Investigator. If the Department of Health and Human Services determines that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not managed or reported by Mitotherapeutix, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

5.11.7 NSF and USDA Reporting Requirements

If Mitotherapeutix is unable to satisfactorily manage a conflict of interest involving NSF or USDA funding, it will appropriately notify the USDA or NSF Office of the General Counsel.

6.0 Responsibilities and Authorities:

Investigators participating in, or planning to participate in the design, conduct, or reporting of research including PHS, USDA, or NSF funded research at Mitotherapeutix have the authority and responsibility for the activities in this policy.

Uncontrolled if Printed

7.1 Records

Mitotherapeutix will maintain all records related to the implementation of this policy for at least three years after:

- the date of creation;
- the date of termination or completion of a research award or contract;
- the submission of the final expenditures report; or
- the date of final resolution of any investigation, audit, or similar action involving the records.

8.0 References:

- 8.1 Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- 8.2 Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- 8.3 National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies
- 8.4 USDA sections 2, 3, and 8 of 2 CFR Part 422
- 8.5 Related Forms/Documents:
 - Financial Conflict of Interest in Research Disclosure Questionnaire
 - Basic Management/Monitoring Plan Process
 - Frequently Asked Questions Regarding Financial COI in Research
 - Research Compliance Committee Charter

ORIGINAL: 4/2021

REVIEWED: 4/2021

REVISED: N/A