



**Medical University of South Carolina (MUSC) Enterprise -
Sponsored Research Significant Financial Interest (SFI) Disclosure Review & Financial Conflict of
Interest (FCOI) Management Procedure**

1.0 Introduction

The Medical University of South Carolina (MUSC) Enterprise maintains [Policy #E-COI-001 \(MUSC-MUHA Conflict of Interest\)](#) to provide a framework for recognizing, disclosing, and managing employee conflicts of interest. The primary goal of this policy is to prevent an employee's activities from adversely influencing MUSC Enterprise operations.

As MUSC conducts research funded by the Public Health Service (PHS) and other federal agencies, it is required by federal law to maintain an appropriate written, enforced policy and/or procedures on conflict of interest that complies with the minimum requirements of 42 CFR Part 50 Subpart F - "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" and 45 CFR Part 94 "Responsible Prospective Contractors" as well as all other relevant policies of federal funding and oversight agencies. Further, per the referenced federal requirements, MUSC is required to make our FCOI policy publicly available/accessible (i.e., posted on the institution's publicly available website; link provided above).

The purpose of this procedure is to document the framework and associated processes, established in accordance with Policy #E-COI-001, utilized by MUSC to specifically ensure compliance with the requirements of the 2011 Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F).

The information provided in this section complies with the requirements of **42 CFR §50.604(a)**.

2.0 Definitions

Economic Interest/Financial Benefit (applies to Employee and "Immediate Family" as defined below): includes anything of monetary or potential monetary value – including but not limited to external income/salary, commissions, fees, honoraria, gifts, equity interests (which includes any stock, stock options, stock grants or warrants, convertible notes, membership or LLC units, or other ownership interest), interests in real or personal property, dividends, royalty, rent, capital gains, intellectual property rights, loans, reimbursed/sponsored travel, and forgiveness of debt. Please note, the MUSC COI requirements also require the reporting of any personal/non-financial interest(s)/benefit(s) to an employee (or immediate family); for example, promise of a job promotion, future grant, research publication, clinical trial or authorship, etc.

Conflict of Interest: relates to situations when an Employee or Immediate Family member receives a business/financial interest or personal benefit related to the employee's position/role in a manner that may inappropriately influence, or may have the appearance of inappropriately influencing, the employee's judgment, compromise the employee's ability to carry out MUSC Enterprise (defined below) responsibilities, or be a detriment to the integrity of the MUSC Enterprise.

Entity: includes but not limited to any domestic or foreign organization or company engaging in business, such as proprietorship, partnership, limited liability company (LLC), or corporation (includes professional trade associations or other similar organizations).



Financial Conflict of Interest (as defined by 42 CFR §50.603): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Immediate Family: includes the employee's parents, spouse, siblings, children, stepchildren, and grandchildren.

Institutional Responsibilities: defined as an employee's professional responsibilities on behalf of MUSC, which may include but not limited to research, teaching or educational activities, clinical care activities, administration, service on institutional boards/committees/panels, etc. For students or trainees, institutional responsibilities are adherence to all applicable MUSC/College/Program policies, rules, and guidelines.

Investigator (as defined by 42 CFR §50.603): means 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 by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

MUSC Enterprise (collectively referred to herein as "MUSC"): includes the Medical University of South Carolina (University), the Medical University Hospital Authority (MUHA), and entities (including but not limited to Medical University of South Carolina Physicians (MUSCP), MUSC Community Physicians (MCP), the MUSC Foundation and the Zucker Institute for Innovation Commercialization), which derive their not-for-profit status from MUSC, MUHA or such other entity.

Outside Activity: defined as but not limited to non-MUSC employment; speaking or presenting on behalf of an entity (e.g., educational programming); serving as a consultant, advisor, or expert; serving as governing board member; serving as an executive/officer; foreign government affiliations; and any other role/relationship that relates to or arises in connection with an employee's institutional responsibilities. These activities may or may not be compensated.

Senior Key Personnel (as defined by 42 CFR §50.603): means the PD/PI 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 by the Institution under this subpart.

Significant Financial Interest (SFI) (as defined by 42 CFR §50.603):

- (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's 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.
- (2) 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

Note: The MUSC Enterprise has established a \$5,000 aggregate threshold related to royalties and reimbursed or sponsored travel when defining an SFI for the institution.

3.0 Training

Per applicable MUSC Enterprise procedures developed in accordance with Policy #E-COI-001, the Institution requires all employees/individuals meeting the NIH definition of "Investigator" (i.e., anyone who is responsible for the design, conduct, or reporting of research) to complete a COI related training program:

- (1) prior to engaging in a sponsored research project/award regardless of the funding source;
- (2) a minimum of every four (4) years; and,
- (3) immediately when any of the following circumstances apply:
 - a) MUSC revises its COI Policy or associated procedures in any manner that affects the requirements of research related personnel;
 - b) an "Investigator" is new to MUSC; or,
 - c) MUSC determines that an "Investigator" is not in compliance with MUSC COI Policy or an established COI Management Plan.

The comprehensive MUSC Enterprise COI related training (i.e., annual mandatory and Collaborative Institutional Training Initiative course) informs all individuals involved in research (i.e., "Investigators") of MUSC COI Policy #E-COI-001; their responsibilities regarding the disclosure of all external business/financial relationships and outside activities regardless of remuneration; and, the PHS Objectivity in Research Rule.

The information provided in this section complies with the requirements of **42 CFR §50.604(b)**.

4.0 Disclosure Requirements

Per MUSC Enterprise Conflict of Interest policies, all applicable employees/individuals meeting the NIH definition of "Investigator" must complete/submit a COI disclosure form reporting all recent (i.e., within the preceding 12 months) and active outside economic interest(s)/financial benefit(s) or activity(ies) (defined above) related to the individual's institutional duties and responsibilities. The COI disclosure form



must be submitted at the time of hire and annually thereafter. In addition, if a new economic interest/financial benefit or outside activity develops, or an existing interest, benefit, and/or activity changes during the year, the individual is required to update their disclosure within 30 days.

The referenced employees/individuals must disclose all foreign (i.e., non-US) economic interests/financial benefits (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country).

Employees are not required to disclose the following:

- Any salary or any other compensation from the MUSC Enterprise (defined above) or the Ralph H. Johnson Department of Veterans Affairs Medical Center. *The exception is that royalties distributed through the Zucker Institute should be reported.
- Income from investment accounts, such as mutual funds and retirement accounts, as long as the employee/individual does not exercise direct control over the investment decisions made in these accounts.
- Income, reimbursed or sponsored travel from seminars, lectures, teaching engagements, service on advisory or review panels for a domestic* 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.
- Research funding awarded to the MUSC Enterprise.

The information provided in this section complies with the requirements of **42 CFR §50.603**, **42 CFR §50.604(b)**, and **42 CFR §50.604(e)(1)-(3)**.

5.0 Disclosure Review and SFI/FCOI Determination Process

Prior to the expenditure of any funds associated with a sponsored research project, the MUSC Office of Research & Sponsored Programs (ORSP) will confirm all Investigators, including applicable subrecipients*, associated with the application/award have a current disclosure (i.e., within the preceding 12 months) on file. In the event a current disclosure is not on file for any listed Investigator, ORSP and/or the MUSC COI Office will immediately notify the applicable Investigator of the requirement to complete a disclosure in order to proceed with the required SFI/FCOI evaluation associated with the application/award.

Subsequent to the disclosure confirmation described above, the ORSP Grants Administrator will provide the MUSC COI Office the proposal and/or award package, including the list of applicable Investigators associated with the proposal and/or award. The COI Office will review the disclosure(s) submitted by all Investigators indicating an external economic interest/financial benefit and/or outside activity to determine if the interest(s)/benefit(s) meets the definition of a Significant Financial Interest (SFI) (defined above).

The COI Office will conduct an initial evaluation to determine if any identified SFI is related to the sponsored research. An SFI is determined to be related to the research when the evaluation determines the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research.



If any SFI is determined to be related to the subject sponsored research, the COI Office will conduct an initial evaluation to determine if it qualifies as a Financial Conflict of Interest (FCOI). An SFI will be considered an FCOI if it is determined the SFI could directly and significantly affect or bias the design, conduct or reporting of the subject research project.

In the event the COI Office cannot readily determine if an (1) SFI is related to the sponsored research and/or (2) the SFI qualifies as an FCOI (e.g., due to no historical precedent, unique/complex issues, etc.) the COI Office will refer the details of the project and associated SFI(s) to the [MUSC Research Conflict of Interest \(RCOI\) Committee](https://web.musc.edu/about/coi/coi-charters) (<https://web.musc.edu/about/coi/coi-charters>) for a determination. The RCOI Committee's decision will be documented in the meeting minutes and maintained by the COI Office.

** - In the event the sponsored research project utilizes subrecipients and/or collaborators, MUSC, as the awardee institution, will establish a written agreement stipulating whether the institution's Financial Conflict of Interest policy and associated procedures or that of the subrecipient applies to the subrecipient's Investigators. If the subrecipient's Investigators must comply with the subrecipient's policy, the subrecipient is responsible for certifying its policy complies with the regulation and reporting all identified FCOIs to MUSC for timely reporting. If the subrecipient's Investigators must comply with MUSC's Financial Conflict of Interest policy, the subrecipient is required to submit all Investigator disclosures of SFIs to MUSC. MUSC will be responsible for all review, management, and reporting obligations in accordance with 42 CFR Part 50 Subpart F, as applicable.*

The information provided in this section complies with the requirements of **42 CFR §50.604(c)**, **42 CFR §50.604(c)(1)(i)-(iii)**, **42 CFR §50.604(d)**, **42 CFR §50.604(f)**, **42 CFR §50.605(a)(1)**, and **42 CFR §50.605(a)(4)**.

6.0 FCOI Management Process

In the event an FCOI is identified for an Investigator/sponsored research project, including applicable subrecipients*, MUSC will develop a Management Plan in order to reduce or eliminate the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. In consultation with the Investigator, the COI Office/RCOI Committee will develop a management strategy that must be acknowledged/agreed to in writing by the subject Investigator, applicable leadership, and any individuals responsible for a documented mitigation measure. Compliance with the FCOI Management Plan will be evaluated by the COI Office annually, at a minimum, until the completion of the sponsored research project.

Potential FCOI management measures include, but are not limited to, the following as applicable to the research and associated interest(s):

- Internal/external disclosure (e.g., research project team/collaborators, students, research subjects, patients, presentations, publications, manuscripts, press releases, etc.)
- Recusal or modification/limitation of role (e.g., prohibit/limit involvement in data collection/analysis, subject recruitment, enrollment/consent related activities; recusal from business/purchasing decisions or specific research related procedures/interventions)
- Modification of the research plan
- Independent monitoring (e.g., non-conflicted statistician)
- Non-conflicted oversight committees or review panels (e.g., independent/non-conflicted Data and Safety Monitoring Board)



- Prohibition on serving as the Principal Investigator or Co-Principal Investigator
- Divestiture of financial interests
- Severance of the relationship associated with the financial conflict

In the event MUSC identifies any SFI which was not timely disclosed by an Investigator or not previously reviewed/evaluated in accordance with the described procedures (i.e., prior to the expenditure of funds), within 60 days MUSC will review the SFI to determine if (1) it is related to the sponsored research and (2) qualifies as an FCOI. If the evaluation determines the interest qualifies as an FCOI, a management plan will be implemented on an interim basis which specifies the current/pending actions to manage the FCOI.

The information provided in this section complies with the requirements of **42 CFR §50.604(g)**, **42 CFR §50.605(a)(1)**, **42 CFR §50.605(a)(3)(i)-(iii)**, and **42 CFR §50.605(a)(4)**.

7.0 PHS FCOI Reporting Requirements

Subsequent to the identification of an FCOI associated with an Investigator involved in PHS funded research, including applicable subrecipients*, MUSC will provide the applicable funding agency with an FCOI report providing details of the FCOI and the associated management strategy. Specifically, the report will contain the following information, at a minimum:

- (1) Project number;
- (2) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (3) Name of the Investigator with the Financial Conflict of Interest;
- (4) Name of the entity with which the Investigator has a Financial Conflict of Interest;
- (5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (6) Value of the financial interest (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;
- (7) A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
- (8) A description of the key elements of the Institution's management plan, including:
 - a) Role and principal duties of the conflicted Investigator in the research project
 - b) Conditions of the management plan
 - c) How the management plan is designed to safeguard objectivity in the research project;
 - d) Confirmation of the Investigator's agreement to the management plan;
 - e) How the management plan will be monitored to ensure Investigator compliance; and
 - f) Other information as needed.

For PHS funded research, the report must be initially submitted to the funding agency prior to the expenditure of funds and annually thereafter. Any new FCOI identified during an existing PHS funded research project (e.g., a new SFI for an Investigator or the addition of a new Investigator to the project team with an FCOI), MUSC will develop/implement a Management Plan and submit the required FCOI to the applicable funding agency within 60 days.

The information provided in this section complies with the requirements of **42 CFR §50.604(h)**, **42 CFR §50.605(b)**, and **42 CFR §50.605(a)(4)**.



8.0 PHS Retrospective Review

For PHS funded research, MUSC will complete a retrospective review within 120 days whenever a FCOI is not identified or managed in a timely manner, including the following occurrences:

- Failure by the Investigator to disclose a SFI that is determined by MUSC to constitute a FCOI;
- Failure by MUSC to review or manage such a FCOI; or,
- Failure by the Investigator to comply with a FCOI Management Plan.

The retrospective review will evaluate the Investigator's research activities associated with the subject research project to determine if there was any bias in the design, conduct, or reporting of the research as a result of the applicable FCOI. MUSC will document the retrospective review, which will include, but not be limited to, the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

In the event the retrospective review identifies bias, MUSC will immediately notify the applicable funding agency and submit a mitigation report providing the key elements described above as well as describe the impact of the bias on the research project and MUSC's completed/planned actions to mitigate or eliminate the impact of the bias.

In addition, if MUSC discovers FCOI related non-compliance associated with PHS funded clinical research specifically conducted to evaluate the safety or effectiveness of a drug, medical device, or treatment, MUSC will require the subject Investigator to (1) disclose the FCOI in each public presentation of the results of the subject research and (2) request an addendum to previously published presentations of the subject research.

The information provided in this section complies with the requirements of **42 CFR §50.605(a)(3)(ii)(A)**, **42 CFR §50.605(a)(3)(ii)(B)**, **42 CFR §50.605(a)(3)(iii)**, **42 CFR §50.606(a)**, and **42 CFR §50.606(c)**.

9.0 Public Accessibility of FCOI Information related to PHS Funded Research

Upon request, MUSC is required to make available information associated with identified FCOIs held by senior/key personnel (as defined by 42 CFR Part 50 Subpart F) relative to PHS funded research. MUSC is required to provide specific information (i.e., FCOI report minimum elements as required by the regulation) relative to such public requests within five (5) days of receipt of the request.

Requests for information must be made in writing to the MUSC COI Office at the following address:



MUSC Conflict of Interest Office
Office of General Counsel
22 WestEdge Street
Suite 300
Charleston, SC 29403

The information provided in this section complies with the requirements of **42 CFR §50.605(a)(5)(i)-(iv)**.

10.0 Maintenance of Records

MUSC will maintain all FCOI related records (e.g., Investigator disclosures, SFI reviews/relatedness determinations, FCOI determinations, retrospective reviews, mitigation activities, etc.) for a minimum of three (3) years from the date of submittal of the final financial report for the subject research project or three (3) years from any applicable alternative date (e.g., final action has been taken on any associated audit, litigation, or claim) as required by 45 CFR §75.361.

The information provided in this section complies with the requirements of **42 CFR §50.604(i)**.

11.0 Sanctions for Non-Compliance

Per Section VIII of MUSC Enterprise [Policy #E-COI-001 \(MUSC-MUHA Conflict of Interest\)](#), violations of MUSC Enterprise policies, including the failure to avoid a prohibited activity or disclose a conflict of interest in a timely manner, will be dealt with in accordance with applicable policies and procedures that may include disciplinary actions up to and including termination of employment.

The information provided in this section complies with the requirements of **42 CFR §50.604(j)**.