

FCOI Policy

[Financial Conflict of Interest on Federal Grants Policy]

I. Purpose

The “Financial Conflict of Interest on Federal Grants Policy” was designed to establish objective standards that provide a reasonable assurance that the design, conduct, and reporting of research funded by federal grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. The policy applies to all faculty and staff involved in federally funded research at Southern Illinois University School of Medicine (SIUSM) - Springfield, herein also referred to as the “School” or the “University”. Carbondale based SOM faculty and staff need to follow Office of Sponsored Projects Administration requirements. The policy was crafted to achieve compliance with federal requirements that all investigators disclose any potential financial conflict of interest (FCOI) to the University prior to undertaking federally funded research. This policy applies to all other externally-funded activity, including federal flow through projects, for which the funding agency requires an FCOI disclosure.

This policy is distinct from and is in addition to the general “Conflict of Interest: Non-University Activities and Financial Interests” policy that applies to the general duties of Staff, Faculty and Administration as employees of SIUSM.

NOTE: The Office of Grants and Contracts will not be able to submit a federal proposal without a recently completed, grant-relevant, FCOI disclosure form (attestation) for all PIs and personnel listed on the proposal.

II. Definitions

The following definitions apply to this policy unless a specific federal policy uses a different definition, in which case that agency's definition will apply.

Disclosure of significant financial interests: an investigator's disclosure of significant financial interests (SFI) to SIUSM.

FCOI: financial conflict of interest; a significant financial interest (SFI), real or perceived, that could directly and significantly affect the design, conduct, or reporting of federally funded research.

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

Investigator: the project director (PD) or principal investigator (PI), co-principal investigator (Co-PI), and any other personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research. This includes, for example, collaborators, consultants, graduate students, and researchers working on the project.

Research: any basic and applied research, including bench research, clinical trials, creative activity (e.g., a published article, book, or book chapter), or product development (e.g., development and testing of a test, drug, or device). As used in this policy, the term includes any such activity for which research funding is applied for or awarded from a federal agency through a grant, contract or cooperative

agreement, including a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.

Significant financial interest (SFI): as defined by PHS includes:

- A. A significant monetary interest exists if the following situations apply to the investigator and/or the investigator's spouse or domestic partner (evidenced by registration or certification as a same-sex partner), and children involving companies that reasonably appear to be related to the proposed research:
 - i. For publicly traded companies, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure. Examples of income include salary, consulting fees, honoraria, paid authorship, stock/stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value).
 - ii. For non-publically traded companies, if income in excess of \$5000 (in aggregate) is received during the twelve months preceding the disclosure, or when **any equity interest** is held (e.g., stocks, stock options, or other ownership interests).
 - iii. If any income is received from intellectual property rights and interests (e.g., patents, copyrights).

- B. Travel paid by any entity **other than** US Federal, state or local governments, US-based institutions of higher education, academic teaching hospitals, medical centers or research institutes associated with institutions of higher education must be disclosed. Paid travel by foreign academic institutions **must be** reported. Travel disclosures will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. The Associate Dean for Research and the Compliance Officer, or their designees, will determine if further information is needed, including a disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the federally funded research.

- C. Significant financial interest **DOES NOT** include the following types of financial interests:
 - i. Salary, royalties, or other remuneration paid by SIUSM to the investigator if the investigator is currently employed or otherwise appointed by the School, including intellectual property rights assigned to the School and agreements to share in royalties related to such rights.
 - ii. 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.
 - iii. Income from seminars, lectures, or other teaching engagements, or from service on advisory panels or review panels from a federal, state, or local government agency, US institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

III. Oversight of Financial Conflict of Interest

- A. The Conflict of Interest Committee (COIC).
Membership of committee will be in accordance with the operating paper of the COIC.

- B. Duties
This committee will review the FCOI attestation forms when a potential SFI has been identified,

determine whether a SFI actually exists, help formulate associated management plans, accept or suggest modifications to manage or eliminate the potential conflicts, and monitor compliance with plans. The committee will submit management plans to the PI (or other conflicted personnel), the Chair of COIC, and Department Chair for approval signatures. Signed plans will be provided to the Office of Grants and Contracts for uploading and/or reporting to granting agency, as needed.

IV. Institutional Responsibilities and Procedures

A. Investigator training.

In order to facilitate compliance with the federal policy, SIUSM will provide online information and, if requested, individual or group training for investigators on collection and evaluation of FCOI forms and enforcement of this policy. New personnel involved in research must complete the online CITI FCOI training at orientation/the time of hire. This includes graduate students, staff, faculty, etc. Training is valid for 4 years.

B. Disclosure requirements.

At the time of submission of a grant to a federal agency, all participating investigators and personnel “responsible for the design, conduct, or reporting of project activities” are required to complete and submit a Financial Conflict of Interest on Federal Grants Disclosure Statement (FCOI attestation) to the Office of Grants and Contracts (Appendix A). Forms will be reviewed by pre-award staff. If a conflict is disclosed, the Office of Grants and Contracts will initiate review and response procedures. All investigators on funded grants must submit an updated FCOI attestation annually prior to each new budget period of the award. This attestation may indicate no FCOI, any conflicts not in existence previously, and/or updated information regarding any previously disclosed significant financial interest (e.g., the updated value or disinvestment of a previously disclosed equity interest). However, any newly acquired FCOI (e.g., through purchase, marriage, or inheritance) must be disclosed within thirty (30) days to the Office of Compliance, via update to the Annual COI Disclosure Form, and to the Office of Grants and Contracts via email at grants@siumed.edu. New personnel added to a federally funded research grant after the start date of the project must complete a FCOI attestation specific to that grant and be up-to-date on CITI FCOI training prior to performing any work on that grant. The project PI and the associated fiscal officer for the grant are responsible for assuring that any new personnel added midstream to a federally funded research grant are compliant with this requirement.

C. Subcontracts.

If the federally funded research involves a subrecipient (e.g., subcontractors or consortium members), SIUSM (as the awardee institution) will take reasonable steps to ensure that any subrecipient investigator complies with the federal policies by:

- i. Establishing in writing with the subrecipient whether the FCOI policy of SIUSM or that of the subrecipient will apply to the subrecipient's investigators.
 - a. If the subrecipient's investigators must comply with the subrecipient's FCOI policy, the subrecipient must certify that its policy is in compliance with federal policies. In the absence of this certification, the agreement will state that subrecipient investigators are subject to the FCOI policy of SIUSM for disclosing significant financial interests that are directly related to the subrecipient's work for the School.
 - b. If the subrecipient investigators must comply with the subrecipient's FCOI policy, the written agreement will specify a deadline for the subrecipient to report all

identified financial conflicts of interest to SIUSM so that the School can provide timely FCOI reports, as necessary, to the relevant federal agency.

- c. Alternatively, if the subrecipient investigators must comply with the SIUSM FCOI policy, the written agreement will specify a deadline for the subrecipient to submit all investigator disclosures of significant financial interests to SIUSM so that SIUSM can provide timely FCOI reports, as necessary, to the relevant federal agency.
- ii. Providing FCOI reports to the federal agency regarding all financial conflicts of interest of all subrecipient investigators must occur prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

D. Review of FCOI and management of conflicts.

An investigator's significant financial interest is related to federally funded research when SIUSM determines that the significant financial interest could reasonably be influenced by the research outcome. A FCOI exists when review determines that the significant financial interest could reasonably, directly, and significantly influence the design, conduct, or reporting of the federally funded research.

- i. If a FCOI disclosure attestation indicates no significant financial interest, the attestation will be maintained by the Office of Grants and Contracts with the application.
- ii. If a FCOI attestation indicates a potential financial conflict of interest, the proposal may still be processed and submitted. The Office of Grants and Contracts may contact the investigator and the respective Department Chair for additional information. Attestations with identified potential FCOI will be forwarded to Compliance Officer and addressed by:
 - a. The investigator and Chair, in conjunction with the Compliance Officer (or designee) will develop a plan to eliminate, reduce, or manage the conflict of interest. The plan will be reviewed by the Conflict of Interest Committee (COIC), which may either accept the plan or require revisions until it is acceptable. If an acceptable plan is not approved by the COIC before funds are awarded, the Committee will notify the Associate Dean for Research and the Office of Grants and Contracts, who will inform appropriate institutional and funding agency administrators, as required by the agency's guidelines. Grant awards will not be released for any expenditures (including Advanced Account Requests) until the conflict is either eliminated or appropriately managed. The School may be required to decline the award if the conflict cannot be resolved or managed.
- iii. If a new conflict arises or an undisclosed conflict is uncovered, the COIC will review and make recommendations within 60 days of the new conflict disclosure or unreported disclosure discovery.

The COIC will review all submitted materials and elimination/management plans and either accept or require modifications to eliminate or manage the conflict. This could involve, at either COIC or investigator request, a meeting with the COIC, including the Chair as needed. The COIC may also seek expert opinions. Investigators may appeal any final COIC decisions in writing within 14 calendar days.

Approaches that could be used to manage a FCOI include, but are not limited to:

- i. Public disclosure of FCOI (e.g., when presenting or publishing the research).

- ii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI.
- iii. Modification of the research plan (may require pre-approvals from funding agency).
- iv. Change in personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- v. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- vi. Severance of relationships that create financial conflicts.

Whenever SIUSM implements a management plan, the COIC will monitor investigator compliance with the management plan on an ongoing basis until completion of the affected federally funded research project. In the event of the discovery of any significant conflicting financial interest subsequent to initial reports to federal agencies, the faculty member and the University will implement a management plan within 60 days and the COIC will complete a retrospective review to determine whether the research was biased, and if so, provide a mitigation report if required by the relevant federal agency.

E. Reporting of conflicts.

SIUSM must certify in each application for funding to which this policy applies that SIUSM has a written and enforced administrative process to identify and manage FCOI and will ensure compliance with all such related federal policies regarding FCOI. SIUSM must provide initial and ongoing FCOI reports to the federal agency, as required. Thus, SIUSM is required to maintain records relating to all investigator disclosures of financial interests and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a FCOI) and all actions under the University's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the federal agency, or as required by the specific agency. SIUSM must also monitor investigator compliance with approved management plans throughout the duration of the funded project.

F. Public accessibility to FCOI information

Prior to the University's expenditure of any funds under a federally funded research project, SIUSM shall ensure public accessibility. Public accessibility requests must be in writing, whether emailed or mailed via US Post concerning any significant financial interest that meets the following three criteria:

- i. The significant financial interest was disclosed and is still held by the investigator as defined by this policy;
- ii. SIUSM has determined that the significant financial interest is related to the federally funded research; and
- iii. SIUSM has determined that the significant financial interest is a FCOI.

Public accessibility requests must be in writing and must include the following:

- the name of the investigator;
- the investigator's title and role with respect to the research project;
- the title of the federally funded research project;
- the federal grant number, if possible.

Requests will be answered in the manner they were received within five business days of receipt by the applicable Conflict of Interest Office and shall include the information

required to be disclosed per 42 C.F.R. Part 50, Subpart F. The information provided will be current as of the date of the correspondence. Updates to investigator SFIs must be made on an annual basis or within 30 days of acquiring a new SFI. In order to access annual updates or new SFIs that are determined to be FCOIs by the institution, a new public accessibility request will be required.

Requests for public accessibility of disclosed FCOIs may be sent to the following:

SIU School of Medicine

Via email: coiadministration@siumed.edu

Via US Post:

SIU School of Medicine

Office of Compliance

201 E. Madison, Room 342

Springfield, IL 62794-9683

G. Enforcement

Investigators will not be able to access funds prior to disclosure of a FCOI and approval of a management plan. Noncompliance must be reported to the appropriate federal funding agency. Certain agencies (e.g., NIH grants for clinical research) require public disclosure of FCOI on all public presentations and publications (including addendums for previously published items) for any funded research that did not comply with federal disclosure regulations. Failure of investigators to comply with this policy, including restrictions emplaced by the management plans, will be grounds for discipline and sanctions under the appropriate University policy or provisions of any applicable Collective Bargaining Agreement.

Approved by SIU School of Medicine Executive Committee: 9/10/18