



Financial Conflict of Interest on Federal Grants Policy

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FCOI Policy

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[The following was approved on May 16, 2012 (as revised 4/7/2014), in accordance with provisions set forth in SIU Carbondale Board of Trustees 2 *Policies* C.3.e.]

I. Purpose

This Financial Conflict of Interest on Federal Grants Policy (hereinafter referred to as the "policy") was designed to promote objectivity in research by establishing standards that provide a reasonable expectation 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. It applies to all faculty and other staff involved in federally funded research. This policy was crafted in response to federal regulations that require that all investigators disclose any potential financial conflict of interest to the university prior to undertaking federally funded research. This policy is applicable to federally funded sponsored project activity at SIU Carbondale including projects funded with federal flow-through, when the sponsoring agency policy requires a financial conflict of interest disclosure.

This policy is distinct from, supplements, and is in addition to the general Conflict of Interest: Non-University Activities and Financial Interests policy which is applicable to the general duties of University Staff, Faculty and Administration while acting as employees of the University.

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: means an investigator's disclosure of significant financial interests (SFI) to SIU Carbondale.

FCOI: means financial conflict of interest or more fully described as 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: means anything of monetary value, whether or not the value is readily ascertainable.

Investigator: means the project director (PD) or principal investigator (PI), co-principal investigator (Co-PI), and any other senior/key personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research, which may include, for example, collaborators or consultants. Investigator status will be determined from the OSPA Proposal Checklist.

OSPA: Office of Sponsored Projects Administration

Research: encompasses any basic and applied research, be it bench work, creative activity (e.g., a published article, book, or book chapter), or product development (e.g., clinical trials, diagnostic test, or drug). As used in this policy, the term includes any such activity for which research funding is available from a federal agency through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.

Senior/key personnel: means the PD/PI and any other person identified as senior/key personnel by SIU Carbondale in the grant application, progress report, or any other report submitted on the research to the federal funding agency by SIU Carbondale under the scope of this policy.

Significant financial interest (SFI): means one of the following:

- A. A significant financial interest exists if the following situations apply to the investigator and/or the investigator's spouse or domestic partner as evidenced by registration or certification as a same-sex partner, children, and immediate relatives (siblings and parents) 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 the 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. Any travel paid for by any entity other than a Federal, state or local government, an institution of higher education, an academic teaching hospital, a medical center or a research institute associated with an institution of higher education must be disclosed. This disclosure will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. In accordance with SIU Carbondale's FCOI policy, the Director of OSPA or their designee 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 federally funded research.

C. Significant financial interest does not include the following types of financial interests:

- i. Salary, royalties, or other remuneration paid by SIU Carbondale to the investigator if the investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University 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, 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.

III. Financial Conflict of Interest Committee

A. Membership

This committee will consist of five members appointed by the Vice Chancellor for Research from a list of names of individuals submitted by the Faculty Senate and Graduate Council. All members of the committee are expected to have demonstrated significant grantsmanship. The chair of the committee will be a tenured faculty member at the rank of Professor. The Director of OSPA or their designee will serve on the committee in an ex-officio capacity.

B. Duties

This committee will review the FCOI forms and the associated management/monitoring and either accept or suggest modifications to manage or eliminate the potential conflicts. The committee will submit their recommendations to the Director of OSPA.

IV. Institutional Responsibilities and Procedures

A. Investigator Training

In order to facilitate compliance with the federal policy, SIU Carbondale is responsible for investigator training, collection and evaluation of FCOI forms, and enforcement of this policy. In addition to making this policy and associated forms available on its web site, training will be provided by OSPA for all investigators prior to engaging in federally funded research. Training must be repeated at least every four years, and immediately when the University revises its FCOI policies or procedures in any manner that affects the requirements of Investigators; an investigator is new to SIU Carbondale; or an investigator is found to be in non-compliance with the University's FCOI policy or management plan.

B. Disclosure requirements

At the time of submission of a grant to a federal agency, all participating investigators are required to fill out and submit a Financial Interest on Federal Grants Disclosure Statement (FCOI form) (available on the OSPA website) to OSPA which will be reviewed by the Director of OSPA or his/her designee. The

Director of OSPA will assess the potential for a conflict and initiate the review and response procedures outlined below. In addition, all investigators must submit an updated FCOI form annually during the period of the award (by deadlines established by OSPA) to include any information that was not disclosed previously to SIU Carbondale, and to include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest). Any newly discovered or acquired significant financial interest (e.g., through purchase, marriage, or inheritance) must be disclosed within thirty days. New Investigators added to a project after the start date of the project must also complete a disclosure form. This includes situations where a non-Investigator employee's status is changed to that of Investigator. New or changed Investigators must also complete the training, as described above.

C. Subcontracts

If the federally funded research involves a subrecipient (e.g., subcontractors or consortium members), SIU Carbondale (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 financial conflicts of interest policy of SIU Carbondale or that of the subrecipient will apply to the subrecipient's investigators.
 - a. If the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall 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 financial conflicts of interest policy of SIU Carbondale for disclosing significant financial interests that are directly related to the subrecipient's work for the University.
 - b. Additionally, if the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the written agreement will specify a deadline for the subrecipient to report all identified financial conflicts of interest to SIU Carbondale so that the University can provide timely FCOI reports, as necessary, to the relevant federal agency.

- c. Alternatively, if the subrecipient's Investigators must comply with SIU Carbondale's financial conflicts of interest policy, the written agreement will specify a deadline for the subrecipient to submit all Investigator disclosures of significant financial interests to SIU Carbondale so that the University 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 consistent with this policy, i.e., 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 SIU Carbondale reasonably determines that the significant financial interest: 1) could be affected by the research, or 2) is in an entity whose financial interest could be affected by the research. A FCOI exists when the University reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the federally funded research. At the time of submission of a grant to a federal agency, all participating investigators are required to fill out and submit a FCOI form along with the proposal and the Proposal/Award Checklist. Signed FCOI forms will be reviewed by the Director of OSPA; outcomes may include:

- i. If a FCOI form indicates no significant financial interest, the forms will be filed at OSPA and copies forwarded to the appropriate dean or director for informational purposes. The proposal will be submitted by OSPA to meet agency deadlines.
- ii. If a FCOI form indicates a potential financial conflict of interest, the proposal will be submitted by OSPA to meet agency deadlines but the Director of OSPA will contact the faculty for additional information. If the Director of OSPA then determines that a conflict of interest does exist, he/she will forward the FCOI form, along with his/her assessment, to the appropriate dean or director. Financial conflicts of interest will be addressed by one of the following approaches:
 - a. The dean (or director) will work with the investigator to develop a management plan to eliminate the conflict of interest. The dean or director will confirm the agreement in writing to the Director of OSPA, who will report the management plan to the Financial

Conflict of Interest Committee. The Committee will notify appropriate institutional and funding agency administrators, as required by the agency's guidelines

- b. If it is not possible to eliminate the conflict of interest, a plan to reduce or manage the conflict must be developed by the investigator in consultation with the dean or director with guidance from OSPA. This plan will then be forwarded to the Director of OSPA who will forward it on to the Financial Conflict of Interest Committee for review and input. The Committee will notify appropriate institutional and funding agency administrators of the conflict, as required by the agency's guidelines as discussed below.
 - c. All conflicts of interest must be resolved and management plans approved by the appropriate institutional administrators before the research project can begin. Grant awards will not be released to the researcher until the conflict is appropriately addressed. In rare cases, the university may be required to decline the award if the conflict cannot be resolved or managed as discussed below.
- iii. If a disclosure of a new conflict arises or the discovery of an undisclosed conflict is uncovered, the Financial Conflict of Interest Committee will review and make recommendations within 60 days of the new conflict disclosure or unreported disclosure discovery.

The Financial Conflict of Interest Committee will review all of the submitted material and either accept or suggest modifications to further eliminate the conflict. This could involve, at either the committee's request or at the investigator's request, a meeting with the committee, involving the dean/director as needed. Expert opinions may also be sought by the committee. The Committee will submit a recommendation to the Director of OSPA who will forward it on to the Vice Chancellor for Research for final approval. Investigators may appeal any final decision in writing within 14 days. Examples of approaches that could be used to manage a FCOI include, but are not limited to:

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

- v. 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.
- vi. Modification of the research plan.
- vii. Change in personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- viii. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- ix. Severance of relationships that create financial conflicts.

Whenever SIU Carbondale implements a management plan, the Financial Conflict of Interest Committee 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 any significant conflicting financial interest that is discovered subsequent to initial reports to federal agencies, the faculty member and the University will implement a management plan within 60 days and the Financial Conflict of Interest Committee 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

The University must certify in each application for funding to which this policy applies, that SIU Carbondale has a written and enforced administrative process to identify and manage financial conflicts of interests and that they will ensure compliance with all such related federal policies regarding FCOI. The University must provide initial and ongoing FCOI reports to the federal agency, as required. Thus, SIU Carbondale 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. SIU Carbondale 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, SIU Carbondale shall ensure public accessibility via its web site of information concerning any significant financial interest disclosed to the University 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. SIU Carbondale determines that the significant financial interest is related to the federally funded research; and
- iii. SIU Carbondale determines that the significant financial interest is a FCOI.

The information that the University must make available via its web site will include the following: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined by normal assessments of fair market value. This posted information will be maintained and updated at least annually by OSPA and will remain accessible for at least three years from the date that the information was most recently updated.

G. Enforcement

Investigators will not be able to access funds prior to disclosure of a FCOI and approval of a management plan. Noncompliance must also 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.