

FCOI Policy

[Financial Conflict of Interest on Federal Grants Policy]

[The following was approved on _____, 2012, in accordance with provisions set forth in SIU 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 all federally funded sponsored project activity at SIU including federal flow through projects.

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.

FCOI: means financial conflict of interest or more fully described as a significant financial interest (SFI) 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 person, 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.

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 in the grant application, progress report, or any other report submitted on the research to the federal funding agency by SIU 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, and dependent children, *involving companies that reasonably appear to be related to the proposed research*:

i) For publically 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'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 to the investigator if the investigator is currently employed or otherwise appointed by SIU, including intellectual property rights assigned to SIU 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. Two of these members should be Associate Deans for Research, departmental chairs, or center directors. 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 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 conflict. 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 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 SIU revises its FCOI policies or procedures in any manner that affects the requirements of Investigators; an investigator is new to SIU; or an investigator is found to be in non-compliance with SIU'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 FCOI form (Appendix A) to OSPA which will be reviewed by the Director of OSPA or their designee (and if a conflict is noted, by the Financial Conflict of Interest Committee). 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, 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.

C. Subcontracts

If the federally funded research involves a subrecipient (e.g., subcontractors or consortium members), SIU (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 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 for disclosing significant financial interests that are directly related to the subrecipient's work for SIU.
 - (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 so that SIU can provide timely FCOI reports, as necessary, to the relevant federal agency.
 - (c) Alternatively, if the subrecipient's Investigators must comply with SIU'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 so that SIU 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 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 SIU 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 dean or unit director; outcomes may include:

- i) If a FCOI form indicates no significant financial interest, the forms can be forwarded directly to OSPA along with the proposal.
- ii) If a FCOI form indicates a significant financial conflict of interest, the proposal will be forwarded on to OSPA to meet agency deadlines but with a flag indicating a possible conflict of interest. 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 before the FCOI form is forwarded to OSPA. The dean or director will confirm the agreement in writing to the Director of OSPA.
 - 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.
 - c) All conflicts of interest must be resolved and management plans approved before the research project can begin.
- 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:

- (i) Public disclosure of FCOI (e.g., when presenting or publishing the research).
- (ii) For research projects involving human subjects research, disclosure of FCOI directly to participants.
- (iii) 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.
- (iv) Modification of the research plan.
- (v) Change in personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- (vii) Severance of relationships that create financial conflicts.

Whenever SIU implements a management plan, SIU 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, SIU 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

SIU must certify in each application for funding to which this policy applies, that SIU 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.

SIU must provide initial and ongoing FCOI reports to the federal agency, as required. Thus, SIU is required to maintain records relating to all investigator disclosures of financial interests and SIU's review of, and response to, such disclosures (whether or not a disclosure resulted in SIU's determination of a FCOI) and all actions under SIU'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 must also monitor investigator compliance with approved management plans throughout the duration of the funded project.

F. Public accessibility to FCOI information

Prior to SIU's expenditure of any funds under a federally funded research project, SIU shall ensure public accessibility via its web site of information concerning any significant financial interest disclosed to SIU that meets the following three criteria:

- (i) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by federal policies;
- (ii) SIU determines that the significant financial interest is related to the federally funded research; and
- (iii) SIU determines that the significant financial interest is a FCOI.

The information that SIU 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 must be updated at least annually 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.

Appendix 1
SOUTHERN ILLINOIS UNIVERSITY

Financial Interest on Federal Grants Disclosure Statement

This form must be completed by all investigators, including the principal investigator, co-investigators, and any other staff member who is responsible for the design, conduct or reporting of project activities. The form must be submitted to your dean or director at the time an application is submitted for external research support.

Name: _____ Dept.: _____ College: _____
Title/Position: _____ Email: _____ Campus Phone: _____
Dean/ Director: _____ Principal Investigator: _____
Sponsor: _____ Proposal Deadline _____
Proposal Title: _____

This Financial Interest on Federal Grants Disclosure Statement is to be completed in compliance with SIU's Financial Conflict of Interest on Federal Grants Policy (add weblink). Please note, answering "yes" to any of the following questions does not mean the financial interest is inappropriate or improper, it means only that disclosure and evaluation, and in some cases, approval and oversight, are required. All thresholds listed below are an aggregate for the investigator, his or her spouse or domestic partner (as evidenced by registration or certification as a same-sex partner), and dependent children. These questions apply to companies that could reasonably appear to be related to the proposed research.

1. Financial Interest in Publically Traded Companies **YES** **NO**

Over the past 12 months, have you received income or obtained other financial interest in excess of \$5000 from a publically traded company that is in any way related to or that might be affected by your proposed research activities? 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). Excluded income includes salary, royalties, or other remuneration paid by SIU while an SIU employee; income from mutual funds not managed by the investigator, and income from lectures, workshops, panels, etc., for universities and state, local, or federal agencies.

2. Financial Income from Non-publically Traded Companies **YES** **NO**

Over the past 12 months, have you receiving income in excess of \$5000 from a non-publically traded company that is in any way related to or that might be affected by your proposed research activities? Examples of income include salary, consulting fees, honoraria, paid authorship.

3. Equity Interests in Non-publically Traded Companies **YES** **NO**

Over the past 12 months, have you held any equity interest in a non-publically traded company that is in any way related to or that might be affected by your proposed research activities?

4. Intellectual Property **YES** **NO**

Have you received any income from intellectual property rights and interests (e.g. from patents, copyrights, or royalty agreements) from any companies in any way related to or that might be affected by your proposed research?

5. SBIR/STTR Phase II **YES** **NO**

Have you held any equity interest in a SBIR/STTR phase II funded company that is in any way related to or that might be affected by your proposed research activities?

If you have answered "yes" to any of the above questions, please work with your Dean/Director to develop a

management plan to eliminate, reduce, or manage your FCOI and attach before forwarding to OSPA. Please note that you may be asked for more specific information.

6. Paid Travel by Companies

YES

NO

Have you received any travel that has been paid for or reimbursed 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?

If you have answered "yes" to Question #6, please provide the following information before forwarding to OSPA. Please note that you may be asked for more specific information.

Purpose of the trip: _____

Destination: _____ Duration: _____

Who sponsored this travel?: _____

Investigator Statement

I have read and understood SIU's Financial Conflict of Interest on Federal Grants Policy and have made all required financial interest disclosures; will submit a proposal for a Conflict of Interest Management Plan if necessary; and will comply with any conditions or restrictions imposed by the University to eliminate, reduce, or manage conflicts of interest regarding my research.

Signature _____ Date _____

TO BE COMPLETED BY DEAN or CENTER DIRECTOR

Were any potential conflicts noted?

YES

NO

If **NO**, forward this form to the Office of Sponsored Projects Administration.

If **YES**, the investigator must propose a management plan to eliminate, reduce, or manage the conflict and you may provide assistance. You must review the plan before forwarding to OSPA. The plan will then be provided to the Research Conflict of Interest Committee for review and recommendation to the Director of OSPA and the Vice Chancellor for Research for final action.

Printed Name: _____ Signature _____ Date _____
Dean or Director

Place completed disclosure form(s) in a sealed envelope and forward to:

Director of OSPA, Office of Sponsored Projects Administration, C206 Woody Hall, Mailcode 4709.