

Institutional Advancement, 500
(Office of Research and Sponsored Programs)

Financial Conflicts of Interest (FCOI)

1.0 Purpose

This policy has been established to identify Financial Conflicts of Interest (FCOI) concerning sponsored programs and to manage them according to federal guidelines. This policy also promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by federal grants, contracts or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest.

2.0 Scope

This policy is applicable to specifically Public Health Service (PHS) funded sponsored project activity at Albany State University (ASU). However, ASU reserves the right to apply this policy to other funding sponsored program sources.

3.0 Policy

It is the policy of Albany State University to abide by federal regulations that require all investigators to disclose any potential financial conflict of interest to the University during the course of undertaking federally funded research.

4.0 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:

Collaborative Institutional Training Initiative (CITI): a subscription service that provides research ethics education to all members of the research community.

Conflict of Interest: the situation in which personal considerations have the potential to compromise or bias professional judgment and objectivity.

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

Financial Conflict of Interest (FCOI): 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: 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.

Investigator's Institutional Responsibilities: an Investigator's professional responsibilities on behalf of and as defined by ASU, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such institutional review boards.

Management Plans: actions taken by the institution to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

The Public Health Service (PHS): the operating division of the Health and Human Services Department (HHS) responsible for promoting the protection and advancement of the American population's physical and mental well-being.

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 or sponsored program for which 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, research resources award.

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

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considered senior/key personnel, to the extent they are responsible for the design, conduct or reporting of the research:

- Professional faculty
- Research associates
- Emeritus faculty
- Subrecipient personnel
- Research collaborators
- Visiting scientists
- Individuals with courtesy appointments
- Undergraduate, graduate, and post doctoral students

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

- A. A significant financial interest exists if the following situations apply to the investigator and/or the investigator's spouse 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 ASU's FCOI policy, the Associate Vice President of ORSP 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:

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

5.0 Procedures

5.1 Financial Conflict of Interest Committee Requirement

Membership

The FCOI Committee will be comprised of:

- General Counsel's Office Representative
- 2 College Deans
- 2 Department Chairs
- 3 faculty members who represent a balance of disciplines, including one representative from the Faculty Senate
- Vice President of Institutional Advancement, ex-officio capacity
- Director of Grant and Contracts, ex-officio capacity
- Research Compliance Officer, ex-officio capacity

This committee will be appointed by the Associate Vice President of ORSP and its members will serve a term of three years. All members of the committee are expected to have demonstrated significant grantsmanship and have training and/or experience related to financial conflict of interest. The chair of the committee will be a tenured faculty member at the rank of Professor. The Investigator may request that an ad hoc member be added to the committee for the purpose of including a representative familiar with the investigator's field. The AVP will appoint the ad hoc member.

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.

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The committee will also review complex disclosures, as requested by ORSP, to assure that all issues have been considered or addressed.

In addition, the committee will review management plans and make recommendations for resolutions upon a disagreement and will submit their recommendations to the Associate Vice President of ORSP

5.2 Required and Annual Disclosures

Investigators and Senior/Key Personnel must submit FCOI disclosures annually or at the time of submission of a grant to a federal agency. Annual submissions will be required in August of each year.

All submitted FCOI forms (ASU's Website) will be reviewed by the Associate Vice President of ORSP and/or their designee (and if a conflict is noted, by the Financial Conflict of Interest Committee).

Any newly discovered or acquired significant financial interest (e.g., through purchase, marriage, or inheritance) must be disclosed by submitting a revised FCOI form to ORSP within thirty days of that change.

5.3 Training Requirements

In order to facilitate compliance with the federal policy, ASU 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 website, training will be provided by the Office of Research and Sponsored Programs (ORSP) for all investigators prior to engaging in federally funded research. Training must be repeated at least every four years, and immediately when

- ASU revises its FCOI policies or procedures in any manner that affects the requirements of Investigators
- an investigator is new to ASU
- or an investigator is found to be in non-compliance with ASU's FCOI policy or management plan.

ASU is requiring that each Investigator and Senior/Key Personnel complete the Conflict of Interest Training Module that is located on the CITI website (<https://www.citiprogram.org/>)

- prior to engaging in research to any PHS-funded grant or contract and
- at least every four years.

5.4 Subcontracts

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

5.5 Review of FCOI and Management of Conflicts

An investigator's significant financial interest is related to federally funded research when ASU reasonably determines that the significant financial interest:

- i. could be affected by the research, or
- ii. is in an entity whose financial interest could be affected by the research.

A FCOI exists when ASU 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

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and Senior/Key Personnel are required to fill out and submit a FCOI form along with the proposal and the Proposal Transmittal.

Signed FCOI disclosure forms will be reviewed by the dean; outcomes may include:

- i. If a FCOI disclosure form indicates no significant financial interest, the forms can be forwarded directly to ORSP along with the proposal and transmittal form.
- ii. If a FCOI form indicates a significant financial conflict of interest, the proposal and transmittal form will be forwarded on to ORSP 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 will work with the investigator to develop a management plan to eliminate the conflict of interest before the FCOI form is forwarded to ORSP. The dean or director will confirm the agreement in writing to the Associate Vice President of ORSP.
 - 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 ORSP. This plan will then be forwarded to the Associate Vice.
 - c. President of ORSP who will forward it on to the Financial Conflict of Interest Committee.
 - d. 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 as needed. Expert opinions may also be sought by the committee. The Committee will submit a recommendation to the Associate Vice President of ORSP who will forward it on to the Provost and Vice President of Academic Affairs for final approval. Investigators may appeal any final decision in writing within 14 days.

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Examples of approaches that could be used to manage a FCOI include, but are not limited to:

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

Whenever ASU implements a management plan, ASU 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, ASU 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. The report will address the impact of the bias on a research project and the actions taken by or to be taken by ASU to eliminate or mitigate the bias.

5.6 Reporting of Conflicts

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

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

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5.7 Public Disclosure

ASU will make this policy available to the general public by posting it on the University's website under the Office of Research and Sponsored Programs.

Prior to ASU's expenditure of any funds under a federally funded research project, ASU shall ensure public accessibility via its website of information concerning any significant financial interest disclosed to ASU 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. ASU determines that the significant financial interest is related to the federally funded research; and
- iii. ASU determines that the significant financial interest is a FCOI.

The information that ASU must make available via its website will include the following:

- Investigator's name
- Investigator's title and role with respect to the research project;
- Name of the entity in which the significant financial interest is held;
- 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.

5.8 Monitoring

ASU may conduct random and for-cause monitoring of FCOI Management Plans.

5.9 Non-Compliance

Failure to comply with this policy or to follow an agreed upon Management Plan will result in a retrospective review and may result in the following actions:

- Termination of the Investigator's external funded project(s) at ASU.
- Termination of Investigator's ability to submit proposals for external funding through ASU.

Violations of this policy include, but are not limited to:

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- Failure to comply with the disclosure process (by refusal to respond; by deliberately responding with incomplete, inaccurate, or misleading information, or otherwise);
- Failure to remedy significant conflicts of interest; and
- Failure to comply with a prescribed management plan.

5.10 Additional Responsibilities

ASU maintains this written Financial Conflict of Interest policy and will implement a process to identify and manage, reduce or eliminate these conflicts.

ASU shall, for any federal research funding from the PHS or any other federal funding agency that imposes FCOI requirements:

- Include in the subaward agreement terms that establish whether this policy or that of the subrecipient will apply to the subrecipient's Investigators and provide FCOI reports regarding subrecipient Investigators to the awarding federal funding agency;
- Maintain records of, and related to, FCOI disclosures;
- Report conflicting significant financial interest to the awarding component of the funding agency;
- Inform the National Science Foundation, Office of the general Counsel if it is unable to satisfactorily manage a Significant Financial Conflict of Interest related to the project funded by NSF;
- Report to the NIH the existence of any conflicting financial interests and assure that the interest has been managed, reduced, or eliminated in accordance with NIH regulations; and
- Maintain records related to Investigators disclosures of financial interests and the institution's review of, or response to such disclosures and all actions under this policy or retrospective review for at least three years from the date of the final expenditures report.

6.0 Accountability

The Office of Research and Sponsored Programs, under the supervision of the Office of Institutional Advancement.

7.0 Contacts

Vice President of Institutional Advancement
Director of Sponsored Programs
Research Compliance Officer

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8.0 References

Office of Extramural Research. (2012, August 2). *Financial Conflict of Interest*. Retrieved August 2, 2012, from U.S. Department of Health and Human Services: <http://grants.nih.gov/grants/policy/coi/>

Portland State University. (May, 31 2012). Financial Conflict of Interest Policy. Portland, Oregon, USA. Retrieved from

Southern Illinois University. (2012, June 25). *FCOI Policy*. Retrieved July 25, 2012, from Policies and Procedures: <http://policies.siu.edu/policies/FOCionFederalGrants.html>

9.0 Last Update

February 5, 2014