Seattle University
Policy for Financial Conflict of Interest Disclosure and Management for Investigators in Externally Sponsored Programs

DEFINITIONS

Compensation for the purposes of this policy means any monetary or other financial benefit from any external entity (non-SU) and does not include SU salary.

Financial Conflict of Interest (FCOI) means the reasonable determination that an Investigator's Significant Financial Interest is related to SU research or sponsored project and could directly and significantly affect the design, conduct or reporting of SU research or sponsored project.

Equity means any ownership interest in any commercial or non-profit entity, including common stock and other equity securities, and any right to acquire any options, warrants or other convertible securities or any other ownership interest. (This does not include 'indirect" equity interest through mutual funds.)

External Entity can be any or all of the following: a natural person (other than yourself) capable of being legally bound, sole proprietorship, corporation, partnership, limited liability company or partnership, limited partnership, for-profit or nonprofit corporation, unincorporated association, business trust, or any other person with legal capacity to contract a governmental agency or governmental subdivision or any other entity whether foreign or domestic that is external to SU.

Family Member means an Investigator's spouse, domestic partner and/or dependent children.

Institutional Responsibilities means the investigator's professional responsibilities on behalf of SU, including research, research consultation, teaching, professional practice, service on SU committees or panels.

Investigator, for purposes of this policy, means the project director, principal investigator or any other person responsible for the design, conduct or reporting of sponsored programs, regardless of the person's title. Those identified as Investigators, for the purposes of this policy are the *Principal Investigator and any person listed by the Principal Investigator on the Proposal Transmittal Form (PTF)) as responsible for the design, conduct, or reporting of their sponsored program(s)*. These individuals must be identified at the time of proposal submission or immediately if an individual later assumes responsibilities of Investigator.

PD/PI means a project director or principal Investigator of a research project; the PD/PI is considered an Investigator for purposes of this policy and also as key personnel, essential to work performance in the contract proposal and contract.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to society, including the sciences, social sciences, and the

humanities. The term encompasses basic and applied research and product development.

Significant Financial Interest (SFI) means one or more of the following interests that reasonably appears to be related to the investigator's institutional responsibilities:

a. Compensation or remuneration that exceeds $5,000 to the investigator or family member in the 12 months preceding the disclosure or any equity interest greater than $5,000 in value received from any publicly-traded external entity, OR

b. Compensation or remuneration that exceeds $5,000 to the investigator or family member in the 12 months preceding the disclosure or any equity interest in *any* non-publicly traded external entity, OR

c. Reimbursed or sponsored travel unless the travel is reimbursed or sponsored by a federal, state or local government entity, 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.

d. ***Significant Financial Interest*** does not mean salary, royalties or other compensation or remuneration paid by Seattle University including royalties from intellectual property assigned to Seattle University, income from mutual funds or other investment vehicles in which the investigator does not directly control the vehicle's investment decisions or income from seminars, lectures or teaching engagement from government agencies, institutions of higher education, academic teaching hospitals, medical centers or research institutes that are affiliated with an institution of higher education.

Sponsored Programs include both research and other programs that receive external funding based upon competitive proposals submitted to local, state, and federal agencies and other organizations. Grants and contracts are managed through the Office of Research Services and Sponsored Projects (ORSSP).

POLICY STATEMENT

Preamble

A conflict of interest is a situation in which personal considerations have the potential to compromise or bias professional judgment and objectivity. A primary category of concern is Financial Conflict of Interest (FCOI). This policy addresses such conflicts.

There are multiple regulations and policies at the federal, state, and university level that require the disclosure and management of conflicts involving financial interests of university faculty and staff.

A separate policy governs Conflict of Commitment concerns that arise out of time allocations between an employee's university responsibilities and his/her work involving external entities. Those are covered by a separate policy. See Faculty Handbook Sections 9.3.1 and 9.3.2.

1.0 OBJECTIVE

This document sets forth University policy on the disclosure, management, and resolution of significant financial conflicts of interest and pertains only to "Investigators" listed by Principal Investigators on the Proposal Transmittal Form (PTF) as responsible for the design, conduct, or reporting of sponsored programs at Seattle University. Sponsored programs include all externally funded programs. Sponsored programs and the PTF are managed through the SU Office of Research Services and Sponsored Projects (ORSSP).

This policy is required by and is intended to establish compliance with the U.S. Department of Health and Human Services (DHHS) regulations (42 CFR Part 50, Subpart F) *Responsibility of Applicants for Promoting Objectivity in Research* and the financial conflict of interest policies of the National Science Foundation (NSF).

2.0 OVERVIEW OF FINANCIAL CONFLICT OF INTEREST

Seattle University and its employees are committed to the principle of free, open, and objective inquiry in the conduct of its teaching, research, and service missions. In the fulfillment of these missions, it is natural that opportunities arise for its faculty and staff to develop relationships with external entities and to explore commercial activities. The University encourages such endeavors as they enhance personal competency and benefit the community and the institution.

These interactions, however, create the potential for financial conflicts of interest where an individual's financial or personal considerations may affect or appear to affect their SU activities related to externally sponsored programs. The existence of a real or apparent financial conflict does not necessarily mean that the activity at issue must be avoided or discontinued. A financial conflict of interest depends on the situation, and not on the character or actions of the individual.

It is through disclosure to Seattle University of significant financial interests related to an Investigator's research or sponsored program that such activities may be reviewed and, if warranted, managed. The identification of significant financial interests does not necessarily imply any improper activities or motives on the part of the Investigator. This policy establishes that disclosure, review, and management process.

3.0 PERSONS TO WHOM THE POLICY IS APPLICABLE

This policy applies to all "Investigators" in externally sponsored programs at SU, as reflected in the institutional responsibilities assigned to or carried out by the Investigator.

Normally, all senior research and project personnel should be listed as "Investigators." All of the following should be considered, to the extent they are responsible for the design, conduct, or reporting of the sponsored program: professorial faculty, research associates, emeritus faculty, research collaborators, visiting scientists, individuals with courtesy appointments. The term "Investigator" does not commonly apply to SU departmental grant administrators or to the financial reporting staff of sponsored programs.

4.0 POLICY

4.1 Required Disclosure to Seattle University Identification of "Investigators"

When Principal Investigators submit funding proposals through ORSSP they must list all "Investigators" (as identified in Section 3.0 of this policy) on their project and ensure that required disclosures to SU from all listed persons have been submitted. Federal regulations require that disclosures and management plans (if needed) be approved prior to expenditure of sponsored funds, if awarded.

An Investigator who begins participating in the research project after the expenditure of funds has begun shall submit a FCOI Annual Disclosure Form and, if necessary, Attachment to the Director of the Office of Research Services and Sponsored Projects (or designee) within 30 days of beginning work on the research project.

Financial Conflict of Interest (FCOI) Annual Disclosure Form and FCOI Disclosure Attachment

Notifications to the University community of this annual requirement will be coordinated by the Office of Research Services and Sponsored Projects (ORSSP). These forms will require only information that is necessary and will not collect unrelated data. Information to be included on these forms is based on the individual's financial activities from the 12 months preceding the submission of the Form.

By May 1st of each year, all "Investigators" (as identified in Section 3.0 of this policy) are required to complete an FCOI Annual Disclosure Form and submit it to the SU Office of Research Services and Sponsored Projects. If a "significant financial interest (SFI)" (see Section 4.2) is identified on the FCOI Annual Disclosure Form, an FCOI Disclosure Attachment must also be completed and submitted. The May 1st disclosure due date enables individuals to use their annual income tax return information, if needed, to complete the form(s). However, the Annual Disclosure Form should reflect any material changes up to the time an Investigator submits the Form.

Required Submission of Revised Forms

If there is a material change (an acquisition of a SFI) to the information provided on the FCOI Annual Disclosure Form and/or FCOI Disclosure Attachment, a new form must be submitted to the SU Office of Research Services and Sponsored Projects within 30 days of that change.

4.2 Significant Financial Interests (SFI)

Investigators must disclose "Significant Financial Interests" in an external entity that:

- Sponsors his/her research or sponsored project;
- Has made or pledged a gift to Seattle University that benefits his/her research or sponsored project;
- Has products, services, or research interests that could reasonably appear to be affected by his/her research or sponsored project;
- Sells goods or services to the University that will be used in his/her research or sponsored project; or
- Has another involvement in his/her research or sponsored project (such as a consulting agreement).

4.3 Public Accessibility Requirements and Confidentiality

This policy shall be posted on the Seattle University website, available on the ORSSP homepage.

The FCOI Annual Disclosure Forms, FCOI Disclosure Attachments, and management plans are considered to be confidential personnel information and should be maintained in a secure and confidential file. The information contained in these documents is available only to individuals duly charged with the responsibility for review and management of financial conflicts of interest at Seattle University and may be released only in accordance with and as required by federal law, Washington law or a lawful court order. The FCOI Annual Disclosure Forms and the FCOI Disclosure Attachments may be copied only by the signer and the ORSSP.

Information concerning identified FCOI's held by senior/key personnel will be made available within five (5) calendar days of receipt of a written request. This information will include:

- The Investigator's name, title and role with respect to the research project;
- The name of the entity in which the SFI is held;
- The nature of the SFI; and
- The approximate dollar amount of the SFI or a statement that the interest cannot be readily determined through public places or other reasonable measures of market value.

This information will include any updates made after the annual disclosure. All requests must be in writing and directed to:

Seattle University
Office of Research Services and Sponsored Projects
901 12th Avenue
USVC 203
P.O. Box 222000
Seattle, WA 98122

Information concerning identified FCOI's shall be made available on request for three years from the most recent update.

Records of and related to FCOI disclosures shall be retained according to University record retention policies and schedules and sponsor requirements

4.4 Disclosure Review, Management Plans, Dispute Resolution and Appeals

Disclosure Review

Office of Research Services and Sponsored Projects will review completed FCOI Annual Disclosure Forms and FCOI Disclosure Attachments, and will notify individuals upon completion of such review.

Prior to expenditure of funds, if ORSSP determines any SFI's related to the research exist and, if any SFI could directly or significantly affect the research or sponsored project, i.e., an FCOI exists, consistent with this policy, a Management Plan will be developed and implemented prior

to expenditure of funds.

If there is a material change to the information provide in a FCOI or an Investigator is new to the research sponsored project, the ORSSP will review the new disclosure, determine if any SFI's related to research exist and, if any SFI could directly or significantly affect the research or sponsored project, i.e., an FCOI exists, consistent with this policy, develop and implement a Management Plan so that ORSSP may report to the granting agency, if required, within 60 days.

If SU identifies an SFI was not disclosed timely by and Investigator or not previously reviewed, the ORSSP will review the new disclosure, determine if any SFI's related to research exist and, if any SFI could directly or significantly affect the research or sponsored project, i.e., an FCOI exists, consistent with this policy, develop and implement a Management Plan within 60 days.

Management Plans

Upon reviewing an Investigator's FCOI Disclosure Attachment, the Director of the ORSSP (or designee), after discussion with the Investigator, will decide if a conflict of interest exists and a management plan is needed. Should management of a potential or actual significant financial conflict of interest be required, the Investigator, the Principal Investigator, as applicable, the head of the responsible unit (or designee), and the Director of the ORSSP (or designee) will work together to draft a "Management Plan." These written plans will manage, reduce, or eliminate the SFI. Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information. Final management plans are reviewed and approved by the Provost.

Management plans may include a single element or several elements such as:

1. Monitoring of the sponsored program by independent researchers or reviewers, or the COI Committee or their designee;
2. Modifications to the research or program plan;
3. Appointment of an oversight panel or person to review research/scholarship;
4. Appointment of an oversight panel or person to monitor the use of students and staff;
5. Change of personnel or personnel responsibilities or disqualification from participation in the portion of the research that would be affected by the SFI;
6. Severance of relationships that create financial conflicts;
7. Public disclosure of SFIs, including to human research participants, researchers, publishers, and/or conference organizers;
8. Limitations on the employee's involvement in personnel decisions on behalf of the University;
9. Transfer of purchasing authority;
10. Reduction or elimination of significant financial interests; and/or
11. Other arrangements that manage, reduce, or eliminate a potential financial conflict of interest.

Dispute Resolution

If the Investigator, the head of the responsible unit (or designee), and the Director of the ORSSP (or designee) cannot agree on a management plan, the matter will be referred to the SU Conflict

of Interest Committee (COIC) (see Section 4.5). In such cases, the Investigator may request that an SU Faculty member of his/her choosing (other than himself/herself) be appointed to the COIC for the review of the Investigator's SFI and appropriate response.

The COIC will review the written materials, consult with the Investigator, the Principal Investigator, as applicable, the head of the responsible unit (or designee), the Director of ORSSP (or designee) and/or others as needed. The COIC will make their recommendation to the Provost. The Provost, after consideration of the COIC recommendation, shall make a determination on management plans reviewed by the COIC. The Provost's decision is final.

4.5 Responsibilities of the Conflict of Interest Committee (COIC)

The SU Conflict of Interest Committee is comprised of tenured faculty members and is staffed by ORSSP personnel.

The COIC has the following primary responsibilities:

1. Reviewing complex disclosures, as requested by ORSSP, to assure that all issues have been considered and addressed;
2. Reviewing draft management plans where the Investigator, the Principal Investigator, as applicable, the head of the responsible unit (or designee) and the Director of OSRRP (or designee) have been unable to reach agreement and make a recommendation for resolution to the Provost; and
3. Advising ORSSP on implementation and communications regarding the FCOI policy and processes.

4.6 Individual Responsibilities for Compliance

Vice Presidents, Associate Provosts, and Vice Provosts, in conjunction with the appropriate Dean and/or Director, as well as SU University Counsel and the Director of ORSSP, will ensure compliance with and enforcement of this policy. They also review and approve management plans as needed. The Provost makes the final determination on management plans that he/she reviews as a result COIC recommendations and/or faculty appeals.

Deans, Center/Institute Directors, and Department Heads are responsible for compliance with and implementation of this policy within their schools or departments. The head of the responsible unit (or designee) is responsible for collaborating with the Investigator, the Principal Investigator, as applicable, and the Director of ORSSP (or designee) in the development, completion, and oversight of management plans within their school, department, center, or institute.

Principal Investigators must list all "Investigators" responsible for the design, conduct or reporting of their sponsored program(s) on the Proposal Transmittal Form (PTF) at the time of proposal submission and ensure that each Investigator files an FCOI Annual Disclosure Form as required. If an "Investigator's" significant financial interest requires a management plan, the Principal Investigator will collaborate with him or her, the head of the responsible unit (or designee) and the Director of ORSSP (or designee) to develop the plan.

Investigators must submit an FCOI Annual Disclosure Form, and if needed, an FCOI Disclosure Attachment, by May 1 of each year and submit a new form within 30 days if there is a material change (an acquisition of a significant financial interest) to the information provided. Should a management plan be required, Investigators will collaborate with the Principal Investigator, as applicable, the head of the responsible unit (or designee) and the DORSSP (or designee) to develop the plan. Investigator responsibilities include adherence to management plans.

Subgrantees, Contractors, and Collaborators, who are working under subagreements from SU that are funded by the Public Health Service (PHS), must comply with the PHS regulations (42 CFR Part 50 Subpart F, grants and 45 CFR Part 94, contracts) by providing appropriate assurances of compliance including written certification that the subgrantee's, subcontractor's, collaborator's or other subrecipient's FCOI is fully compliant with federal regulations. Compliance with federal regulations shall be a material term in the subgrantee's, contractor's, collaborator's or other subrecipient's written agreement with SU. All subagreements covered under this paragraph must contain a provision stating that if the subgrantee, subcontractor, collaborator or other subrecipient cannot provide such certification, the Director of ORSSP may declare the subagreement void or may require the subgrantee, subcontractor, collaborator or other subrecipient to comply with SU's FCOI policy for disclosing SFIs that are directly related to the work for SU. Additonally, all subagreements must contain requirements that all subgrantees, subcontractors, and collaborators must report identified financial conflicts of interest to the Director of ORSSP in sufficient time to permit SU to fulfill its reporting obligations

4.7 Monitoring

ORSSP conducts random and for-cause monitoring of FCOI management plans. Monitoring of management plans will continue on an ongoing basis until the research project is complete.

4.8 Remediation and Sanctions

Failure to comply with this policy may prevent individuals from submitting applications for external funding until they have complied even if that results in untimely submissions.

Failure to comply with this policy may subject an SU employee to sanctions up to and including dismissal.

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

a. Failure to comply with the disclosure process (by refusal to respond; by deliberately responding with incomplete, inaccurate, or misleading information; or otherwise);
b. Failure to remedy FCOI; and
c. Failure to comply with a prescribed management plan.

ORSSP will monitor compliance with this policy.

If the research or sponsored project involved a Public Health Service funded research project of clinical research to evaluate the safety or effectiveness of a drug, medical device or treatment and an Investigator who designed, conducted or reported the research or sponsored project had an FCOI that was not managed or reported consistent with federal laws and regulations, the

Investigator must disclose the FCOI in each public presentation of the results of the research or sponsored project and request an addendum to any previously published presentations to disclose the FCOI.

4.9 Retrospective Review

If ORSSP identifies a SFI that was not disclosed timely by an Investigator, it shall review the SFI, determine if it is related to a research and sponsored projects and if there is a FCOI. If an FCOI exists, ORSSP may implement a Management Plan on an interim basis while a permanent Management Plan is developed.

If an FCOI is not identified or managed in a timely manner either as a result of an Investigator's failure to disclose a SFI, by SU's failure to review or manage a FCOI or by the Investigator's failure to comply with the FCOI Management Plan, within 120 days of determination of the non-compliance, SU either through the ORSSP or by the Provost's designee will complete a retrospective review of the Investigator's activities and the research or sponsored project to determine if any research conducted during the period of non-compliance was biased in its design, conduct or reporting. SU make take any necessary interim measures until the retrospective review is completed and any permanent actions to respond to any FCOI are implemented.

The retrospective review will document at a minimum:

a. Project number and Title;
b. PD/PI or contact PD/PI if more than one;
c. Name of the Investigator with FCOI;
d. Name of the entity with which the Investigator has a FCOI;
e. Reason for the retrospective review;
f. Detailed methodology used for the retrospective review; and
g. Findings and conclusions of the review.

If a retrospective review results in changes to a previously submitted FCOI report, SU will update the report, specifying actions necessary to manage the FCOI. If bias is found, SU will report to the research or project sponsor and prepare a mitigation report. In addition to submitting the retrospective review, SU will submit the mitigation report, including a description of the impact of the bias and a description of the plan of action or actions necessary to eliminate or mitigate the effect of the bias.

5.0 ADDITIONAL RESPONSIBILITIES

5.1 Responsibilities of Seattle University

The University maintains this written financial conflict of interest policy and will implement a process to identify and manage, reduce or eliminate conflicting significant financial interests.

For any federal research funding from the Public Health Service or any other federal funding agency that imposes these requirements, the University shall:

a. Require subgrantees, contractors, and collaborators working under PHS funded subagreements from SU to comply with the PHS regulations (42 CFR Part 50 Subpart F,

§ 50.604 [grants] and 45 CFR Part 94, § 94.4 [contracts]) by following this SU policy or by providing the appropriate assurances of compliance and timely reporting to SU;

b. Maintain the records of and related to FCOI disclosures according to the SU record retention policies and schedules and sponsor requirements. Records shall be maintained by the University for no less than five (5) years after the termination or completion of the research to which they relate and no less than 3 years from the date the final expenditure report is submitted to the granting agency, whichever is longer;
c. Report any conflicting significant financial interest to the awarding component of the funding agency that issued the award prior to the expenditure of funds and that the interest has been managed, reduced, or eliminated;
d. Report to the awarding component of the funding agency any significant financial interest identified as conflicting, subsequent to the initial disclosure, and that the interest has been managed, reduced or eliminated within 60 days of that identification;
e. Report to the awarding component of the funding agency within 60 days, a revised FCOI if necessary upon the identification of an Investigator who is newly participating in the research;
f. Report any update to a previously submitted FCOI following a retrospective review;
g. Make information available, upon request, to the sponsoring agency regarding all identified conflicting interests and how those interests have been managed, reduced or eliminated;
h. Inform the National Science Foundation, Office of the University Counsel, if it is unable to satisfactorily manage a significant financial conflict of interest related to a project funded by the NSF;
i. Notify the funding agency promptly if bias is found and submit a mitigation report;
j. Notify the funding agency promptly if an Investigator fails to comply with this policy or a management plan appears to have biased the design, conduct or reporting of a research project;
k. Provide the opportunity for any SU employee to seek information or request advice on possible financial conflicts of interest without being required to disclose his or her name or identifying details of the potential conflict. Any unit of the University may request advice about a potential financial conflict of interest from ORSSP provided that no more identifying information than necessary should be disclosed unless required by law or University policy;
l. Conduct required training of all Investigators; and
m. Post information required on its publicly accessible website.

5.2 Responsibilities of SU Offices

The Provost is responsible for the implementation of this policy and provides oversight of the following research units:

Institutional Review Board (IRB) queries all Investigators submitting new, continuing, or modification protocols regarding whether those individuals have completed an FCOI Annual Disclosure Form. IRB notifies ORSSP of any Investigators who have not submitted Disclosure Forms.

Office of Research Services and Sponsored Projects (ORSSP) provides assistance and guidance to Faculty and other SU employees, Supervisors, Department Heads, Directors, Deans, Vice Provosts, Vice Presidents, and the Conflict of Interest Committee throughout the FCOI disclosure, review, approval and management processes. The ORSSP fulfills the functions described in Section 4.0 of this policy. The ORSSP provides training and guidance materials in FCOI regulations, requirements and obligations.

The Office of Research Services and Sponsored Projects (ORSSP) prepares the annual report to the Seattle University system as well as any other reports required by state, federal or other oversight agencies. The ORSSP will do this in conjunction with the appropriate Vice President Vice Provost and/or Senior Vice Provost, the Chief Financial Officer, the Provost President and the Office of the University Counsel.

Office of the University Counsel, as designated by the Office of the President, advises the SU Conflict of Interest Committee and the SU administration in the FCOI review and management processes. In conjunction with the appropriate Department Head, Director, Dean, Vice President and Vice Provost, as well as the ORSSP, the Office of the University Counsel facilitates compliance and enforcement of this policy.

5.3 Training

The Office of Research Services and Sponsored Projects (ORSSP) has made online training available through the Collaborative Institutional Training Initiative (CITI). All SU Investigators must complete this training:

- Prior to engaging in any externally sponsored research;
- At least every four years; or
- Immediately, if:
    - An Investigator is new to SU;
    - An Investigator is not in compliance with this policy or a management plan developed under this policy;
    - Changes in this policy affect the requirements for Investigators.

ORSSP will send a message to each Investigator by April 1 of each year with information about this program, federal regulations requiring this policy and the Investigator's obligations under this policy, including the Investigator's duty to report any SFI by May 1.

Note: Portions of this policy have been adapted from and are used with the permission of the University of Oregon.

ISSUED BY:
Office of Research Services and Sponsored Projects