FINANCIAL CONFLICT OF INTEREST POLICY

I. Policy Statement

Portland State University (PSU) is 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 faculty, staff and students to develop relationships with external entities and to explore commercial activities. PSU encourages such endeavors as they enhance personal competency, enrich instruction, 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 PSU 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.

It is through disclosure of Significant Financial Interests (as defined below) to PSU that such activities may be reviewed and, if warranted, managed. This policy establishes the process of disclosure, review and management.

II. Reason for Policy/Purpose

This document sets forth PSU’s policy on the disclosure, review, management and resolution of Financial Conflicts of Interest and pertains to Principal Investigators and their designated Senior/Key Personnel.

This policy is required by, and is intended to establish compliance with, the US Public Health Service (PHS), National Institutes of Health Regulation (42 CFR Part 50, Subpart F) “Promoting Objectivity in Research.” It is also intended to establish compliance with the National Science Foundation (NSF) and other granting agencies’ policies on Conflict of Interest.

III. Applicability

This policy applies to all persons, including PSU employees, PSU undergraduate, graduate or post-doctoral students, subrecipient personnel, collaborators and consultants, who are involved with externally sponsored programs at PSU and meet the definition of “Investigator” or “Senior/Key Personnel” as defined below.
IV. Definitions

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

2. **Financial Interest.** Anything of monetary value, whether or not the value is readily ascertainable.

3. **Financial Conflict of Interest (FCOI):** A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.

4. **Investigator.** The Project Director or Principal Investigator, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of funded or proposed research, which may include, but is not limited to, students, subgrantees, contractors, consortium participants, collaborators or consultants.

5. **Institutional Official.** The Institutional Official in charge of PSU’s FCOI Policy and process is the Associate Vice President for Research.

6. **Investigator’s Institutional Responsibilities.** An Investigator’s professional responsibilities on behalf of and as defined by PSU, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

7. **Management Plans.** Actions taken by the institution to address a 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.

8. **Senior/Key Personnel.** The Project Director/Principal Investigator, Co-Principal Investigator, and any other persons listed on PSU’s Proposal Internal Approval Form (PIAF) at the time of submission or in a grant application, progress report, or any other report of a proposed or funded research project. All of the following may be considered Senior/Key Personnel, to the extent they are responsible for the design, conduct or reporting of the research: professorial faculty, research associates, emeritus faculty, subrecipient personnel, research collaborators, visiting scientists, individuals with courtesy appointments, as well undergraduate, graduate and post-doctoral students. The term does not commonly apply to PSU departmental research administrators or research administrative professionals.

9. **Significant Financial Interest (SFI).** A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:
With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option or other ownership interest as determined through reference to public prices or other reasonable measures of a fair market value;

With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or

Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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. Disclosure information must include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Institutional Official 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 research.

**SFI does not include** the following types of financial interest: salary, royalties, or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; any ownership interest in the institution held by the Investigator, if the institution is a commercial or for profit organization; 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; income from seminars, lectures or teaching engagements sponsored by 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; or income from service on advisory committees or review panels for 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.
V. Policy Procedure

1. Required and Annual Disclosure to PSU

1.1 Investigators must submit disclosures annually or at the time of a funding proposal submission. When Investigators submit funding proposals through the Office of Research and Strategic Partnerships (RSP), they must list all other Investigators and Senior/Key Personnel on their project and ensure that required disclosures have been submitted to PSU from all listed persons.

1.2 Additionally, in September of each year, Investigators and Senior/Key Personnel are required to complete a FCOI Disclosure Form and submit it to RSP. If a FCOI is indicated on the FCOI Disclosure Form, the FCOI Details Disclosure Form must also be completed and submitted. Notifications to the university community of this annual requirement will be coordinated in RSP.

2. Required Submission of Revised Forms to PSU

If there is a material change (an acquisition of a SFI) to the information provided on the FCOI Disclosure Form and/or the FCOI Details Disclosure Form, a new form must be submitted to RSP within 30 days of that change.

3. Outside Employment Forms

Investigators and Senior/Key Personnel who are required by this policy to complete the FCOI Details Disclosure Form will also be required to submit a copy of their Request for Approval for Outside Employment Form.

4. Management Plans

4.1 Upon reviewing an Investigator’s FCOI Details Disclosure Form, the Research Integrity Director will decide whether a Management Plan is needed. Should management of a potential or actual FCOI be required, the Research Integrity Director will work with the Investigator to draft a Management Plan. The Research Integrity Director will confer with any other appropriate parties, such as the Associate Vice President for Research, the Director of Innovation & Intellectual Property (IIP), and the head of the academic unit as needed to draft the Management Plan. If the parties involved are in agreement, the Associate Vice President and the Investigator will approve the Management Plan. The Associate Vice President can request that a complex Management Plan be reviewed by the FCOI Committee. If the parties involved do not reach an agreement, the FCOI Committee will review the Management Plan and make a recommendation to the Vice President for RSP.
4.2 These written plans will manage, reduce, or eliminate the FCOI(s). Such plans may also address the use of university facilities, involvement of students and overlap between private and university activities. Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, and protect the sensitivity of disclosed information.

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

- Monitoring of the sponsored program by independent researchers or reviewers, or the FCOI Committee or their designee
- Modifications to the research or program plan
- Appointment of an oversight panel or person to review research/scholarship
- Limitations on the employees’ involvement in personnel decisions on behalf of PSU
- Divestiture of SFI(s) and/or
- Other arrangements that manage, reduce, or eliminate a potential FCOI

5. Responsibilities of the FCOI Committee

5.1 The FCOI Committee will be compromised of:

- The Associate Vice President for Research
- A General Counsel’s Office Representative
- At least two PSU faculty members who represent a balance of disciplines and have training and/or experience related to Financial Conflict of Interest in research.

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 FCOI Committee will be appointed by the Vice President for RSP and staffed by RSP personnel.

5.2 The FCOI Committee has the following primary responsibilities:

Reviewing complex disclosures, as requested by RSP, to assure that all issues have been considered and addressed.

Reviewing draft Management Plans where the Investigator, the head of the responsible academic unit (or designee), and the Associate Vice President for Research have been unable to reach an agreement and making a recommendation for resolution of the disagreement to the Vice President for RSP.

The Vice President, after consideration of the FCOI Committee recommendation shall make the final determination on Management Plans.
6. **Retrospective Review**

PSU is required by federal regulation to conduct a retrospective review in those cases of non-compliance with the federal regulations. This must be done within 120 days of PSU’s determination of non-compliance. PSU will notify the awarding agency promptly and submit a report to the awarding agency in cases where bias is found. The report will address the impact of the bias on a research project and the actions taken by or to be taken by PSU to eliminate or mitigate the bias.

7. **Monitoring**

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

8. **Non-Compliance**

8.1 Failure to comply with this policy or to follow an agreed upon Management Plan will result in a Retrospective Review (described above) and may result in the following actions:

- Termination of Investigator’s external funding project(s) at PSU.
- Termination of Investigator’s ability to submit proposals for external funding through PSU.

8.2 Failure to comply with this policy may subject a PSU employee to other disciplinary processes within PSU and OUS in accordance with Oregon Administrative Rules and with the terms of the AAUP contract.

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

- 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 FCOI; and
- failure to comply with a prescribed Management Plan.

9. **Training Requirement**

Each Investigator and Senior/Key Personnel must complete Conflict of Interest training prior to engaging in research related to any PHS-funded grant or contract and at least every four years. In addition, training must be completed immediately under the following circumstances:

- PSU FCOI policies change in a manner that affects Investigator requirements.
• An Investigator is new to PSU.
• PSU finds an Investigator noncompliant with the institutional policy or his/her Management Plan.

At the time of training, Investigator and Senior/Key Personnel shall provide acknowledgement that they have read and understand this policy.

RSP will make available tools and training opportunities.

10. Public Disclosure

10.1 PSU will make this policy available to the general public by posting it on the University’s Policy Library website and the RSP website.

10.2 PSU is required by federal regulation to make certain information about FCOIs related to PHS-funded research by Senior/Key Personnel available to the public. PSU will do so by responding to any request for information about these specifically covered FCOIs within five business days. Information that must be made available is:

• Investigator’s name
• Investigator’s title and role with respect to a research project
• Name of the entity in which the SFI is held
• Nature of the SFI
• Approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,000; $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through references of public prices or other reasonable measures of fair market value).

11. Additional Responsibilities

11.1 PSU maintains this written FCOI Policy and will implement a process to identify and manage, reduce or eliminate these conflicts.

11.2 PSU 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 the records of, and related to, FCOI disclosures;
• report conflicting SFI 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 FCOI related to a 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 Investigator 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 expenditure report.

VI. Links To Related Policies and Forms

1. Financial Conflict of Interest Disclosure Form

2. FCOI Disclosure Details Form

3. FCOI Supplemental Disclosure Form for PHS Researchers

4. Outside Employment Policy and Form

VII. Links To Related Information

1. NIH

2. NSF

VIII. Contacts

If you have any questions on the policy or procedure for FCOI you may:

1. Call Lorraine McConnell, Research Integrity Director, RSP, at (503) 725-5484
2. Send an email to fcoi@pdx.edu

IX. History/Revision Dates

Origination Date: August 24, 2012

Last Amended Date: Month, Day, Year

Next Review Date: Month, Day, Year
X. Policy Adoption

Approved
PORTLAND STATE UNIVERSITY PRESIDENT
Date 8/5/12

Approved
PORTLAND STATE UNIVERSITY GENERAL COUNSEL
Date 8/15/12