

Washington State University Ethics, Conflict of Interest, and Technology Transfer

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INTRODUCTION

1. Purpose

To promote integrity and objectivity in University research, including research funded by federal grants or cooperative agreements, and to meet regulatory requirements.

2. Scope and Implementation

This policy applies to all University employees, collaborators, and subrecipients (subcontractors, subgrantees) who are responsible for the design, conduct, or reporting of research or the transfer of University technology and/or associated expertise into the private sector. These individuals must comply with the University's policy to disclose financial interests, cooperate with the University processes, and abide by any management plan adopted to manage conflicts of interest (COI).

The Vice President for Research is primarily responsible for the implementation of this University policy.

3. Provisions That Apply

The University must comply with all applicable COI regulations and laws. Those laws have differing standards and procedures. Public Health Service (PHS) regulations on COI have different standards and procedures than the regulations of other federal agencies. COI in technology transfer standards differ because technology transfer implicates the Ethics in Public Services Act, RCW 42.52. This policy includes provisions to satisfy each of these various standards: PHS funding COI provisions, COI provisions applicable to all other research projects, and provisions to manage COI in technology transfer.

- a. PHS funding components require that before applying for or using funding from a PHS funding component, the University must fully satisfy the provisions of the PHS COI regulations. PHS funding components include, among others, the National Institutes of Health, the Health Resources and Services Administration, and the Centers for Disease Control and Prevention.

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INTRODUCTION (cont.)

3. Provisions That Apply (cont.)

- b. As federal sponsors implement specific COI regulations, the University is to update its procedures, as appropriate. If non-PHS regulations are materially different than PHS regulations, this policy is to be updated accordingly.
- c. In addition, the state of Washington has provisions in the Ethics in Public Service Act, *RCW* 42.52, which allow the University to establish an administrative process to manage COIs that arises from technology transfer activities of "research employees."

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DEFINITIONS

1. **Clinical Trial** means any research that assigns human subjects to intervention and comparison groups to study the relationship between a medical intervention and a health outcome.
2. **Conflict of Interest (COI)** means a significant financial interest held by an investigator or research employee and/or specified members of his or her family which could affect the design, conduct, or reporting of research and scholarship activities.
3. **Disclosure of Significant Financial Interests** means disclosure of significant financial interests to WSU. Disclosures are required for research employees to be protected within the Ethics and Public Service safe harbor provisions for technology transfer activities.
4. **Equity Interest** means stocks, stock options, ownership, partnership or limited liability company, or other ownership interests. Equity interest does not include interest in a mutual fund or other stock management vehicle not under the individual's control, but does include interest held in a deferred compensation plan that is under the individual's control.
5. **Family** means the investigator's or research employee's spouse/domestic partner, dependent children, and other dependent relatives living in his or her household (investigator's/research employee's financial interest includes the aggregate financial interest of the family).
6. **Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
7. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
8. **Gift** means anything of received of economic value without giving adequate consideration. A gift of greater than \$50 from an outside entity is a significant financial interest and must be disclosed if it is from an entity that may be affected by the recipient's technology transfer activities or research. (The law provides exceptions for gifts from persons such as family members.)
9. **Honorarium** means money or thing of value offered for a speech, appearance, article, or similar item or activity in connection with a state employee's official role.
10. **Investigator** means the project director or principal investigator, the co-principal investigators, and any other person, regardless of title or position, including the PD/PI and senior/key personnel as defined in this policy, who is responsible for the design, conduct, or reporting of a research project, funding, or proposal.
11. **Investigator's WSU Responsibilities** means an investigator's professional responsibilities on behalf of the University, which may include, for example, activities such as research, research consultation, teaching, professional practice, and institutional committee memberships.

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DEFINITIONS (cont.)

12. **Manage** means taking action to address a COI, which can include reducing or eliminating the COI, to ensure, to the extent possible, that the design, conduct, and reporting of research is free from bias.
13. **Nonconflicting Institution** means the University, a federal, state, or local government agency, an institution of higher education as defined at 20 *USC* 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
14. **PD/PI** means a project director or principal investigator of a research project; the term "investigator" in this policy includes a PD/PI.
15. **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS, including the National Institutes of Health (NIH).
16. **PHS Awarding Component** is a division of the Public Health Service (PHS), such as NIH, that funds the research.
17. **Remuneration** means 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 reasonable measures of fair market value.
18. **Research** means a systematic scientific investigation designed to develop or contribute to generalizable knowledge including basic and applied research as well as associated instruction, scholarly, creative, public service, product development, and extension activities. When PHS funding is applied for or used, *research* includes any activity for which research funding is available from a PHS awarding component.
19. **Research Employee:** The following may qualify as research employees:
 - a. University employees who are responsible for the design, conduct, or reporting of research, including research scientists, postdoctoral research associates, professional staff, and graduate students.
 - b. Appointees without formal employment status who are obligated to follow the University *Faculty Manual* and the University policies and procedures. This may include visiting scientists and faculty with appointments in the professorial ranks whose terms of employment and advancement include contributions via scholarly research.
 - c. Faculty or administrative staff who directly manage the technology transfer process on behalf of the University including the Vice President for Research, the Director, Office of Commercialization, and the Director, Office of Research Support and Operations.

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DEFINITIONS (cont.)

20. **Senior/Key Personnel** means the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS. The term *investigator* in this policy includes senior/key personnel.
21. **Significant Financial Interest (SFI)** means a financial interest of the investigator and/or the investigator's family that is the amount and type which must be disclosed to the University or which creates a COI for the investigator or research employee. The University and most federal sponsors have specific provisions establishing what constitutes SFI.
22. **Small Business Innovation Research (SBIR) Program** means the extramural research program for small businesses established by a federal agency under *Public Law 97-219*. In this policy, *SBIR Program* includes the Small Business Technology Transfer (STTR) Program.
23. **Sponsor** means the entity which has or will provide financial support for the research, which may include corporate sponsors, state agencies, the University, or agencies of the federal government, including the Public Health Service (PHS).
24. **Technology Transfer** means the research employee's interaction with and investment in external entities in an attempt to transfer University intellectual property, technology, and know-how into the private sector of the economy. Technology transfer includes use of specialized skills developed in research to start or contribute to a private business in a field related to the research employee's WSU responsibilities.
25. **Travel Disclosure** includes the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

WASHINGTON STATE UNIVERSITY
EXECUTIVE POLICY MANUAL

Executive Policy #27

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MANAGEMENT OF COI

1. Conflict of Interest Review Committee

- a. The Conflict of Interest Review Committee (COIC) is a presidential committee which reviews all pertinent documentation, disclosures of significant financial interests, and COI resolution plans for potential or actual COI cases based on federal and state law and University policy. The COIC has the responsibility and authority to (1) assess whether a COI exists, (2) assess the extent of the COI, and (3) manage, reduce or eliminate the COI before approving the research.
- b. The investigator or research employee, in collaboration with the COIC, must develop a suitable management strategy for an identified COI. The management plan may include monitoring of the plan and/or a retrospective review and a mitigation report pursuant to PHS or other federal sponsor's regulations.
- c. The COIC establishes bylaws which govern its procedures. The COI application is available at the Office of Research Assurances' COI website.

2. COI That Must Be Eliminated

- a. Some COI is not allowable in a management plan. In sections b, c, and d below, the term *participate* means the actions of approving, disapproving, making decisions regarding, or making recommendations of contract terms.
- b. Honorariums are not permitted when:
 - i. The person offering the honorarium is seeking or is reasonably expected to seek a contract or subcontract with the University and the University employee who is offered the honorarium is in a position to participate in the terms of that contract or subcontract. An investigator is presumed to participate in a contract or subcontract related to his or her research, as is anyone negotiating, managing, or substantially performing the agreement, contract, or subcontract.
 - ii. The person offering the honorarium is regulated by the University and the University employee is in a position to participate in that regulation.
 - iii. The person offering the honorarium is seeking or opposing or is reasonably likely to seek or oppose enactment of administrative rules or actions or policy changes by the University and the University employee may participate in that process.
- c. COIs may not be managed if the investigator or research employee participates on the University side of a contract or subcontract and also participates for the other party. A principal investigator is presumed to participate in a contract or subcontract related to his or her research, as is anyone negotiating, managing, or substantially performing the contract or subcontract.
- d. COI which violate federal or state law or professional ethical standards may not be managed unless the violation of law can be entirely eliminated.

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MANAGEMENT OF COI (cont.)

3. Management Plans

- a. A management plan may include, but is not limited to:
 - i. Public disclosure of financial COI
 - ii. For human subjects research, disclosure of COIs directly to participants
 - iii. Independent monitoring to protect the research against potential bias
 - iv. Modification of the research plan
 - v. Change of personnel or 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 COI
- b. If the investigator or research employee disagrees with the COIC, he or she may ask the Vice President for Research to review the decision.
- c. The University monitors compliance with the management plan until the completion of the research project or technology transfer activity.

4. Failure to Comply

Failure to comply with this policy and any management plan adopted under this policy may result in action under federal or state law and University policy against the investigator or research employee. Faculty may also be subject to discipline under the *WSU Faculty Manual*.

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SIGNIFICANT FINANCIAL INTEREST

1. PHS Funding Component

- a. When applying for or using PHS funding, an SFI is a financial interest of the investigator and or the investigator's family which reasonably appears to be related to the investigator's WSU responsibilities. The University must receive all disclosures before a funding proposal is submitted to PHS.
- b. When applying for or using PHS funding, an SFI that must be disclosed exists if:
 - i. The value of remuneration received from a publicly-traded entity in the 12 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;
 - ii. The value of remuneration received from a non-publicly-traded entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator and/or the investigator's family holds any equity interest in a non-publicly-traded entity;
 - iii. The values above should include any intellectual property rights and interests (e.g., patents, copyrights), held by the investigator and/or the investigator's family upon receipt of income related to those rights and interests;
 - iv. Any travel reimbursed or sponsored (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 the investigator's WSU responsibilities; except travel that is reimbursed or sponsored by a nonconflicting institution; *or*
 - v. All gifts received from an entity other than a nonconflicting institution during the 12 months preceding the disclosure if the aggregate value of the gifts exceeds \$50.
NOTE: Gifts greater than \$50 from nonconflicting institutions may be prohibited under Washington State law. See *RCW 42.52*.

NOTE: Do not include salary, royalties, or other remuneration paid by the University if the investigator is currently employed or appointed by the University; 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 nonconflicting institution; or income from service on advisory committees or review panels for a nonconflicting institution or a research institute that is affiliated with an institution of higher education.

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SIGNIFICANT FINANCIAL INTEREST (cont.)

2. For Other Funding

- a. SFI for research funded by entities other than PHS

Under this subsection, an SFI exists if the value of any financial interests in or remuneration from a business enterprise received by the investigator and/or the investigator's family in the 12 months preceding the disclosure exceeds \$5,000 or represents more than five percent ownership interest for any one enterprise or entity. **Other than the dollar value of SFI that must be disclosed, the same standards and rules regarding determination of SFI apply.**

NOTE: Do not include remuneration from the University; income from seminars, lectures, or teaching engagements sponsored by nonconflicting institutions; income from service on advisory committees or review panels for nonconflicting institutions; or investments in mutual funds, regardless of value.

- b. SFI for Technology Transfer

Refer to [SFI—Technology Transfer](#).

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DISCLOSURE

1. PHS SFI Disclosure

- a. SFI disclosure is to be reported to the WSU Office of Research Assurances before the proposal is submitted to PHS.
- b. Submit an updated disclosure of SFIs at least annually, which includes any information that was not disclosed initially to COI Committee.
- c. Submit an updated disclosure of SFIs to the COI Committee (COIC) within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- d. The COIC, or subcommittee thereof, reviews the investigator's SFI disclosures for actual and potential COIs.
- e. Records of disclosures: see [FCOI Reports to PHS](#).
- f. 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 as defined at 20 *USC* 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The disclosure is to include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The institutional official(s) decide if further information is needed, including a determination or disclosure of monetary value, in order to ascertain whether the travel constitutes an FCOI with the PHS-funded research. Refer to *BPPM* 95.05.

2. General Research Disclosure

- a. Faculty's outside consulting and professional activities are disclosed as provided in the *Faculty Manual* (Sections IV D and F) and *BPPM* 60.44. COI information must be updated annually. In addition, any COI that arises during the course of a research project must be disclosed within 30 days.
- b. The University maintains records, identifiable to each research project, of COI disclosures, determinations by the COIC, and the actions taken to manage the COI. The records must be maintained for at least three years beyond the termination or completion of the research. If a federal or state agency is reviewing the research or the conflict management, the records must be maintained for three years beyond such review.

3. Disclosure for Technology Transfer COI

Refer to [Disclosure of COI-TT](#).

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RETROSPECTIVE REVIEW/MITIGATION PLAN

1. Retrospective Review Process

- a. If during an ongoing PHS-funded research project, the University finds that an SFI has not been disclosed timely or was not previously reviewed by the COIC, the University's designated official(s) are to, within sixty days, determine whether the SFI is related to PHS-funded research and/or determine whether a FCOI exists, and, if so:
 - i. Implement a management plan to manage the COI going forward;
 - ii. Determine if the untimely disclosure was due to investigator noncompliance, and if so:
 - iii. Complete a retrospective review within 120 days, including a determination whether the COI biased the PHS-funded research project.
- b. The review report is to include all of the following information, at minimum:
 - i. Project number
 - ii. Project title
 - iii. PD/PI or contact PD/PI if a multiple PD/PI model is used
 - iv. Name of the investigator with the COI
 - v. Name of the entity with which the investigator has a financial conflict of interest
 - vi. Reason(s) for the retrospective review
 - vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
 - viii. Findings of the review
 - ix. Conclusions of the review

If appropriate, the University amends any previously submitted COI report and specifies the actions that are to be taken to manage the COI.
- c. If bias is found, the University must notify the PHS awarding component promptly and submit a mitigation report that includes the review report, a description of the impact of the bias on the research project, and the plan of action to eliminate or mitigate the effect of the bias.

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RETROSPECTIVE REVIEW/MITIGATION PLAN (cont.)

1. Retrospective Review Process (cont.)

- d. The University may impose reasonable interim measures to the investigator's participation in the PHS-funded research project between the time the University discovers there is undisclosed SFI or COI and the completion of the retrospective review, as the University deems necessary.
- e. Whenever the University implements a management plan based on noncompliance that requires a retrospective review, the University monitors compliance with the management plan until the completion of the PHS-funded research project.

2. Failure to Fully Comply

- a. If the failure of an investigator to comply with the disclosures required by this policy or with a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the University promptly notifies the PHS awarding component of the corrective action taken or to be taken.
- b. The PHS may ask for records created under this policy at any time, regardless of whether or not a disclosure resulted in the University's determination of a financial conflict of interest. The University is required to submit, or permit on site review of, all records pertinent to compliance with this part. The PHS awarding component has the authority to issue a stop work order via the contracting officer or take other enforcement action based on its review of those records.
- c. In any case in which the Department of Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with a financial conflict of interest that was not managed or reported by the University as required by this part, the University is to require the investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

3. Report to Funding Component

- a. Reporting of financial COI.

Before spending any funds under a PHS-funded research project, the University must provide to the PHS awarding component a COI report on any investigator's SFI that the University determines to be a COI and ensure PHS that a management plan for that COI has been implemented. If the COI has been eliminated prior to the expenditure of PHS-awarded funds, the University is not required to submit a COI report to PHS.

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RETROSPECTIVE REVIEW/MITIGATION PLAN (cont.)

3. Report to Funding Component (cont.)

- b. The report must include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the University's management plan. The report is to include all of the following information, at minimum:
 - i. Project/contract number
 - ii. PD/PI or contact PD/PI if a multiple PD/PI model is used
 - iii. Name of the investigator with the financial conflict of interest
 - iv. Name of the entity with which the investigator has a financial conflict of interest
 - v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
 - vi. Value of the financial interest in dollar ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000; or a statement that the interest's value cannot be readily determined through reasonable measures of fair market value
 - vii. A description of how the financial interest relates to the PHS-funded research and the basis for the University's determination that the financial interest conflicts with such research
 - viii. A description of the key elements of the management plan, including:
 - A. Role and principal duties of the conflicted investigator in the research project
 - B. Conditions of the management plan
 - C. How the management plan is designed to safeguard objectivity in the research project
 - D. Confirmation that the investigator agrees to comply with the management plan
 - E. Monitoring of the management plan to ensure investigator compliance
 - F. Other information as needed
- For any COI previously reported regarding an ongoing PHS-funded research project, the University must provide an annual COI report that addresses the status of the financial conflict of interest and any changes to the management plan.
- c. If HHS determines that a PHS-funded project to evaluate a drug, medical device, or treatment was conducted by an investigator with a COI that was not disclosed or managed, HHS may require the investigator to disclose the conflict in each public presentation of the results of the research.

Washington State University Ethics, Conflict of Interest, and Technology Transfer

UNIVERSITY RESPONSIBILITIES

1. WSU Must Have and Enforce a COI Policy

- a. The University must make this policy available via a publicly-accessible website;
- b. The University must inform each investigator of this policy, the investigator's responsibilities under this policy, and of the PHS regulations; and
- c. The University must require each investigator to complete training regarding the same before participating in PHS-funded research and at least every four years, and immediately when:
 - i. The University revises its policy or procedures in any manner that affects the investigator's responsibilities under this policy;
 - ii. An investigator is new to the University; or
 - iii. The University finds that an investigator violates this policy or a management plan.

2. Subrecipients

- a. A subrecipient must abide by this policy or a comparable policy of the subrecipient's own, and take reasonable steps to ensure that any subrecipient investigator complies with COI policy.
- b. A subrecipient must be familiar with and comply with the University's policy to disclose financial interests, cooperate with the University COI processes, and abide by any management plan adopted by the University to manage COIs.
- c. The subcontract must include terms requiring a subrecipient to comply with this policy or have a policy that is effective in practice and that satisfies PHS COI regulations and the regulations of any other federal sponsor.
- d. A subrecipient applying its own policy must certify in the subcontract that its policy complies with COI regulations.
- e. If a subrecipient's investigators must comply with this policy, the subcontract must specify time(s) for the subrecipient to submit disclosures of SFIs to the University.
- f. The University provides COI reports to the PHS awarding component regarding all financial COIs of all subrecipient investigators prior to the expenditure of funds and/or within 60 days of any subsequently identified FCOI.

Washington State University Ethics, Conflict of Interest, and Technology Transfer

UNIVERSITY RESPONSIBILITIES (cont.)

3. Certify to the PHS Awarding Component

- a. The University has a written and enforced process to identify and manage, reduce, or eliminate conflicting interests;
- b. Before spending any funds under the award, the University reports to the PHS awarding component the existence of COI and assures that the COI are managed, reduced, or eliminated, as provided in this policy; and
- c. Upon request, the University makes information available to HHS regarding all conflicting interests and how those interests have been managed, reduced, or eliminated.
- d. The COIC reviews to determine the existence of COI and take actions to ensure that the COI are managed, reduced, or eliminated;
- e. The University provides for retention of COIC review records for at least three years from the date of submission of the research project's final expenditures report or other dates as specified in 45 *CFR* 74.53(b);
- f. The University establishes adequate enforcement mechanisms and sanctions where appropriate; and
- g. The University's written process includes *A Review of Disclosure Forms* section that provides:
 - i. Guidelines for the designated official(s) to identify COI and take actions to ensure that they are managed, reduced, or eliminated; and
 - ii. Examples of conditions or restrictions that might be imposed to manage COI.

4. FCOI Reports to PHS

- a. Prior to spending any funds under a PHS-funded research project, University sends the PHS awarding component a COI report that includes any investigator's COI and assurance that a management plan has been implemented. No report is required if any COI was eliminated prior to the expenditure of PHS funds.
- b. Any COI identified after the University's initial COI report and during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), must be reported (along with a management plan) within 60 days to the PHS awarding component. If the COI report involves an SFI that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed or managed by University (e.g., was not timely reviewed or reported by a subrecipient), the University must complete a retrospective review and, if appropriate a mitigation plan.

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UNIVERSITY RESPONSIBILITIES (cont.)

4. FCOI Reports to PHS (cont.)

- c. Any COI report must include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the management plan. The report must include all of the following information, but is not limited to:
 - i. Project number
 - ii. PD/PI or contact PD/PI if a multiple PD/PI model is used
 - iii. Name of the investigator with the FCOI
 - iv. Name of the entity with which the investigator has a FCOI
 - v. Nature of the financial interest
 - vi. Value of the financial interest in dollar ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$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 reference to reasonable measures of fair market value
 - vii. A description of how the financial interest relates to the PHS-funded research and the basis for University's determination that the financial interest conflicts with such research
 - viii. The key elements of the management plan, including:
 - A. Role and principal duties of the conflicted investigator in the research project
 - B. Conditions of the management plan
 - C. How the management plan is designed to safeguard objectivity in the research project
 - D. Confirmation that the investigator has agreed to the management plan
 - E. The nature of monitoring to ensure investigator compliance with the management plan
 - F. Other information as needed

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UNIVERSITY RESPONSIBILITIES (cont.)

4. FCOI Reports to PHS (cont.)

- c. The report must include (cont.):
 - ix. University must provide an annual FCOI report to PHS that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual report must specify whether the financial conflict is still being managed or explain why it no longer exists.

5. Transparency

- a. Prior to spending PHS funding, University ensures public accessibility, by written response to any requestor within five business days of a request, of information concerning any SFI disclosed to University that:
 - i. The investigator previously disclosed and still holds;
 - ii. The University determined was related to the PHS-funded research; and
 - iii. The University determined is a FCOI.
 - A. The University provides information to the requester within five business days of a request. The information includes the investigator's name, title, role on the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$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 using reasonable measures of fair market value.
 - B. Information concerning the SFIs remain available for responses to written requests for at least three years from the date that the information was most recently updated.

Washington State University Ethics, Conflict of Interest, and Technology Transfer

POLICY FOR MANAGING CO-TECHNOLOGY TRANSFER

1. Introduction

- a. Technology transfer through research employees' involvement in private enterprise is a valuable method of transferring University-created knowledge and technologies into the economy. In addition to standard licensing arrangements, technology transfer is accomplished when research employees engage with private enterprise, among other ways, as employees, owners, investors, or suppliers of technical advice.
- b. A safe harbor for technology transfer activities is included in provisions of the Ethics in Public Service Act, RCW 42.52. These provisions apply only to technology transfer activities of research employees as a special class of University employee. The Act provides that the University may have an administrative process to manage approved private use of University facilities, equipment, and staff time to advance the University's technology transfer mission. Disclosure of conflicting interests and activities is required for research employees to be protected within the Ethics and Public Service safe harbor provisions for technology transfer activities.
- c. A management plan for a conflict of interest in technology transfer (COI-TT) is developed as provided in this policy. COI-TT is the existence of an interest which may reasonably be determined to affect or appear to affect the design, conduct, or reporting of research. COI-TT is **not limited to financial interests** but may include the existence of various ethical and commitment situations. The research employee must perform his or her University duties and the technology transfer activities ethically, legally, and professionally. The research employee must disclose COI-TT and minimize the potential that the outside professional activity may damage the University's academic integrity, mission, or interests.
- d. The Washington State Executive Ethics Board has the authority to review violations of this policy when the Ethics in Public Service Act is violated.

2. Duties and Responsibilities

- a. The University is to:
 - i. Ensure that appropriate administrators are aware of and have approved the research employee's technology transfer activities.
 - ii. Manage any COI-TT.
 - iii. Manage all intellectual property disclosed to the Office of Commercialization (OC). The University will not take equity ownership in a private start-up enterprise that utilizes University intellectual property. The OC has policies related to its equity ownership in start-up companies and avoidance of any institutional COI-TT.

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POLICY FOR MANAGING CO-TECHNOLOGY TRANSFER (cont.)

2. Duties and Responsibilities (cont.)

- b. The research employee is responsible to:
 - i. Fully disclose any SFI or other potential, actual, or perceived COI-TT to the research employee's supervisor, chair, or when appropriate, to the Vice President for Research, chancellor, dean, or director.
 - ii. Comply with all applicable University policies, including the *Faculty Manual*, intellectual property policy, and research regulations and policies.
 - iii. Fully disclose any COI-TT to everyone working on his/her research or related research, including co-investigators, research assistants, trainees, fellows, or students, and to subcontractors working on related research.
 - iv. Cooperate with the COIC and the Office of Research Assurances in reducing, eliminating, or managing the COI-TT.

3. SFI—Technology Transfer

- a. A SFI exists under the technology transfer COI policy if the research employee and/or the research employee's family:
 - i. Receive aggregate fees for consulting, gifts, and/or honoraria in excess of \$1,000 in any 12-month period in the past 24 months from an external entity whose financial interest would reasonably appear to be affected by the outcome of the research employee's research;
 - ii. Have an interest in an external entity that exceeds \$5,000 in fair market value, an ownership interest in any single entity in excess of five percent, receive compensation from an external entity in excess of \$5,000 during a calendar year, or have intellectual property rights and royalties from such rights in excess of \$5,000 per year; or
 - iii. Have **any** financial interest that reasonably may be affected by the outcome of the research employee's research if that research involves clinical trials or other human subject research which requires review by the full Institutional Review Board.
- b. Note: Do not include remuneration from the University, income from seminars, lectures, or teaching engagements sponsored by nonconflicting institutions, income from service on advisory committees or review panels for nonconflicting institutions, or investments in mutual funds, regardless of value.

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POLICY FOR MANAGING CO-TECHNOLOGY TRANSFER (cont.)

4. Disclosure of COI-TT

- a. When engaged in technology transfer, including formation of a start-up company, the research employee must disclose actual or perceived COI-TT to his or her chair or supervisor using the COI application available from the Office of Research Assurances COI website. The research employee must disclose all outside professional activities and SFIs in his or her field or discipline. The research employee must also provide all information to the COIC which can reasonably assist in development of a management plan.
- b. The COI-TT disclosure form must be completed, reviewed, and approved by the appropriate dean, chancellor, director, chair, and/or supervisor prior to engagement in an activity with potential for COI-TT. The disclosure and approval must occur prior to receiving any wage, fee for services, honoraria, or other compensation from the outside entity. Disclosure should be made within five working days of the start of the technology transfer activity. A chair, dean, or other administrator disclosing professional activities, SFIs, or COI-TT under this policy is to submit the disclosure to his or her immediate supervisor.
- c. The chair or supervisor that receives the disclosure is to review the disclosure and evaluate the potential COI. The chair or supervisor also reviews the activity under WSU *Faculty Manual*, Policy on Compensated Outside Service by Faculty Members (Section IV.D.) and/or Policy on Extended Professional Activities (Section IV.E.), and decides whether to approve or disapprove the activity. If the chair or supervisor approves the activity, the chair or supervisor forwards all relevant information and the disclosure to the appropriate dean or chancellor. If the activity is approved at the college and department level, but the college or department reasonably determines the technology transfer activity may give rise to an actual or perceived COI-TT, the matter is to be referred to the Office of Research Assurances on behalf of the COIC.
- d. A research employee must update his or her COI-TT information annually, in accordance with *BPPM* 60.44.
- e. **Note:** Scholarly activities alone are not generally considered *consulting* or *outside employment*. Such activities need only conform to the standards in the *Faculty Manual* or, for nonfaculty investigators and research employees, the applicable employment contract or policy.

5. Principles in Evaluating and Managing COI-TT

- a. Outside professional activity related to a research employee's field or discipline is a critically important method of technology transfer. Faculty members may perform such outside activity under the provisions of the *Faculty Manual*. Other employees are to consult the terms of their employment to determine what activities are allowable.

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POLICY FOR MANAGING CO-TECHNOLOGY TRANSFER (cont.)

5. Principles in Evaluating and Managing COI-TT (cont.)

a. Outside professional activity (cont.)

Outside consulting agreements are personal employment agreements, regardless of whether compensation is provided for the activities. The research employee may wish to seek personal legal advice prior to signing any such agreement. Although consulting agreements may require the consultant to assign all patentable discoveries to the external entity, **a University employee cannot transfer intellectual property to an outside entity if the University has ownership rights in that intellectual property unless that transfer has been approved by the Vice President for Research.** University research employees who are presented with such agreements must not assign or agree to assign intellectual property in violation of University policy.

b. The COIC reviews COI-TT in the same manner as COI with respect to research or funding proposals. In addition, the COIC is to consider the following:

- i. The University's costs must be either de minimis or the activity must be a pre-approved outside professional activity.
- ii. The University must be reimbursed for all costs which are more than de minimis pursuant to a contract with the University for use of facilities or resources. If the contract only uses existing University resources, a facility use agreement (enterprise account) may be used; if the contract includes deliverables such as experimental design or data analysis, a contractual, sponsored program agreement (orso.wsu.edu/forms-templates/), which includes a description of expectations and deliverables, is to be executed. In no instance may the University be reimbursed by the research employee or the outside private entity designating such reimbursement as a gift to the University.
- iii. The research employee's relationship to the private enterprise or start-up must not impair the rights of any graduate or undergraduate student or University employee. **A research employee must never allow outside interests to impair a student's best interests, including right to publish, progress toward degree, or opportunities for related training and experience.**
- iv. The safety and health of a research subject must never be compromised. A COI-TT related to research involving human subjects must be disclosed to University's Institutional Review Board (IRB) for consideration in the IRB review of the project.
- v. Specific stipulations regarding research support by the start-up company must be satisfied.

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5. Principles in Evaluating and Managing COI-TT

b. COIC considerations (cont.):

- vi. Related University policy allows the start-up company to support research projects at the University in the research employee's lab provided that:
 - A. Appropriate University offices, including the Office of Research Support and Operations, the Office of Commercialization, the Office of Research Assurances, and the Office of Finance and Administration work closely to collectively determine that private use is acceptable under tax law and does not conflict with grant requirements or existing University obligations. Such offices consult, as appropriate, with the University's legal council.
 - B. All projects which include a potential COI-TT must have COIC determination that a COI-TT does not exist or that the COI-TT can be appropriately managed prior to facility use.
 - C. A project must be approved by the appropriate college and department administrators and the research employee must comply with established University approval mechanisms, such as the REX form.
 - D. The project must not compromise or interfere with research projects underway in the research employee's lab or with any University function.
 - E. If any employee(s) of the start-up company wish to be included as named participants on any research contract with the start-up company, the request is to be referred to the COIC. The COIC determines whether the integrity of the research will be compromised by the proposal and if the COI-TT can be managed, reduced, or eliminated.
 - F. Inventions arising from University research are owned by the University as provided in the *Faculty Manual* and University intellectual property policy. Joint inventor status may be possible if company employees separately contribute to the invention.
 - G. Students (as opposed to employed graduate research assistants in the research employee's lab) are not permitted to function as employees of the start-up company without obtaining prior permission from the chair/director, dean, chancellor (as appropriate), and Provost. The students must be free to pursue publication, advance in their line of study, and publish their thesis or dissertation without restriction.

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POLICY FOR MANAGING CO-TECHNOLOGY TRANSFER (cont.)

6. Travel To Promote Technology Transfer

Technology transfer is a fundamental part of the University's mission and the University can usually fund travel to pursue research collaborations and explore opportunities for University technology transfer through intellectual property licensing. Travel must be justified and reimbursed following the University travel policies, including the University's policy on travel paid by third parties. Refer to *BPPM* 95.16 for the policy on third-party reimbursement for travel.

7. Use of University Resources For Technology Transfer Activities

Generally, state employees may not use state property, equipment, or other resources for their private benefit or the private benefit of a third party. The COIC may approve a management plan that includes use of University property, equipment, or resources for a research employee's outside activity if the use benefits the University, a management plan includes the use, and the use is approved in advance. Unless the cost to the use is de minimis, the University must be fully compensated at a fair market rate.

Use of WSU resources in technology transfer typically take the form of an approved sponsored research or service center use agreement. Such agreements must justify why the work is being conducted as an outside activity or consultancy rather than an agreement between the sponsor and the University and must articulate how the work advances technology transfer. An agreement permitting private use of resources in the outside consulting or professional activity must be executed prior to the use of University resources for private activities.

It is anticipated that the University employee engaged in outside consulting or professional activity pays the same price for the resources as charged to other entities and sponsors, including appropriate F&A fees.

Contracts between the University and the research employee to use University resources based on this policy are not considered a conflict of interest if the University also makes those resources available to other members of the public at the same cost. The exception is when the resources are in the research employee's lab, or when the research employee (or family) has direct input in the scheduling or the availability of a resource.

8. De Minimis Use Of University Resources in Technology Transfer Activities

- a. The revised Ethics in Public Service Act, *RCW* 42.52.360(2)(c) recognizes that limited personal use of University resources by a research employee for technology transfer activities will not undermine public trust and confidence and can advance the mission of the University.

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POLICY FOR MANAGING CO-TECHNOLOGY TRANSFER (cont.)

8. De Minimis Use Of University Resources In Technology Transfer Activities (cont.)

- b. If the technology transfer activity and the planned use of University resources has prior approval by the COIC (via a management plan), the appropriate supervisor, department chair, and dean, a research employee may use his or her personally-assigned offices, telephones, computer, e-mail account, internet connections, and comparable types of personally-assigned equipment to conduct outside technology transfer activities if the use:
 - i. Is of little or no additional cost to the University;
 - ii. Is reasonable in duration and frequency and is the most effective use of time or resources;
 - iii. Does not interfere with the performance of the official duties of the research employee, other University employees, or students;
 - iv. Does not disrupt or distract from the conduct of University business due to volume or frequency;
 - v. Does not disrupt other University employees and does not obligate other University employees to make unauthorized uses of University resources; and
 - vi. Does not compromise the security or integrity of University property, information, or IT network.
- c. The following resources may be used for outside technology transfer activities only under a contract or sponsored research agreement between the outside entity and the University and if the COIC has approved that contract as part of a management plan.
 - i. Long-distance or other toll calls or use of a University cell phone.
 - ii. Paper and other University consumables.
 - iii. Time of another University employee during the employee's assigned work.
 - iv. Assistance of a graduate student.
 - v. University laboratories, laboratory supplies, or hardware.
 - vi. University research support including but not limited to grant and sponsored project administration, regulatory committee review and monitoring, health and safety units, specialized office and publishing equipment, vivarium, greenhouses, agricultural research stations, pastures, and feeding stations.
 - vii. Equipment that is assigned to another University employee or student.
 - viii. University-owned intellectual property.