

GIM 10

Significant Financial Interest Disclosure Policy

UNIVERSITY OF WASHINGTON
Office of Research
Office of Sponsored Programs
GRANTS INFORMATION MEMORANDUM 10

Revised April 10, 2007

SUBJECT: Policy for Disclosure and Management of Significant Financial Interests Related to Research and Technology Transfer Transactions

SUPERSEDES: GIM 10 (October 29, 2003)

[General Policy](#)

[Background](#)

[Summary of Process](#)

[Definitions](#)

[Principles](#)

[Guidelines](#)

[Other Relevant University Policies and Procedures](#)

I. General Policy

No research or technology transfer activities occurring at the University of Washington shall be adversely affected by the financial interests of persons involved in those activities. Prior to participating in a research or technology transfer activity, anyone having a significant financial interest related to the activity shall disclose the details of the interest to the University. The Office of Research shall be responsible for reviewing disclosures and instituting an adequate plan for the management of any potential conflicts of interest. The ultimate goal of this policy is to protect the integrity and credibility of activities related to research and technology transfer and to maintain public trust and confidence in the University and its employees.

All research and technology transfer transactions undertaken at the University shall be conducted in full compliance with all University policies and all applicable federal and state laws pertaining to conflicts of interest, including applicable rules and regulations of the United States Department of Health and Human Services (HHS) and the United States National Science Foundation (NSF) and RCW Chapter 42.52, the Washington State Ethics in Public Service Act, including, but not limited to, RCW 42.52.360(2)(a).

Persons failing to comply with this policy shall be subject to sanctions as provided herein and by applicable University policies and rules.

II. Background

The competitiveness of the United States and the State of Washington in the global marketplace depends on the

efficient transformation of research into new products, services and technologies. Enhancing our national competitiveness, as well as our national security, requires effective interaction among the federal government, industry, and research universities. Federal policy clearly favors promotion of these governmental, university, and industry relationships in research and technology transfer. In order to encourage the ethical transfer of technology for the economic benefit of the State of Washington, the Washington Legislature enacted 2005 Wash. Laws Ch. 106 ("2005 Ethics Act Amendment"), which amended the Washington State Ethics in Public Service Act ("Ethics Act") to allow the University to develop, adopt, and implement, upon approval by the Governor, administrative processes that apply in place of the obligations imposed on universities and University Research Employees under specified sections of the Ethics Act. This Significant Financial Interest Disclosure Policy has been adopted by the University and approved by the Governor in accordance with the provisions of the 2005 Ethics Act Amendment codified at RCW 42.52.220(1) and 42.52.360(2)(a).

The policies and incentives favoring collaboration also make stewardship of research and technology transfer transactions at the University complex and challenging, particularly when the safety and well being of human subjects is involved. The benefits of research to the nation's health and economy must not be compromised by conflicts of interest that have the potential to produce bias in the design, conduct, or reporting of the research or to distort technology transfer transactions. At the same time, it must be recognized that both significant human and economic costs will be incurred if the benefits of useful research are unreasonably delayed.

The policy and procedures set forth here seek to maintain an appropriate balance among all of these competing interests by establishing effective mechanisms to identify and manage significant financial interests that may influence research or distort technology transfer transactions.

This policy is intended to establish compliance with two legal requirements. First, it is consistent with the rules adopted effective October 1, 1995 by HHS and NSF requiring that grantee institutions adopt, maintain and enforce written policies pertaining to financial conflicts of interest of research investigators. Second, it implements an administrative process that creates an exemption for complying University employees under RCW 42.52.030(2) of the Washington State Ethics in Public Service Act.

III. Summary of Process

Significant Financial Interests (as defined below) shall be disclosed on the Significant Financial Interest Disclosure Form (Exhibit 1) under the following circumstances: 1) by an investigator when a proposal for a research project is first submitted to the Office of Sponsored Programs, 2) by an investigator when a human subjects application is first submitted to the Human Subjects Division, 3) by an Investigator prior to engaging in any unsponsored, unfunded, or similar research, 4) by an Investigator when a Significant Financial Interest arises during the course of research, or 5) by an Inventor (upon the request of UW TechTransfer), prior to the conclusion of a license transaction with a licensee.

It is the Principal Investigator's responsibility to ensure that those with financial interests in research are identified and make required disclosures in conjunction with the submission of a research proposal or application for human subjects approval. In technology transfer transactions, UW TechTransfer will be responsible for the identifying and obtaining disclosures from all those who have a significant financial interest in the proposed transaction.

The Significant Financial Disclosure Form and supporting materials are forwarded to the Office of Research for review. The Office of Research, acting through the Vice Provost for Research or designee, will be responsible for evaluating and instituting a plan for managing the financial interests that have been disclosed, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Reviews will generally not be completed by the Office of Research until after the proposal has been funded or until after a technology transfer transaction has been agreed upon in principle. Most reviews are completed within 30 days following submission of complete materials.

Advance approval is required prior to engaging in research. The review must be completed before any expenses are incurred under an award, before any research can begin, and before any license agreement can be completed. In the event the Office of Research concludes that a conflict cannot be eliminated or managed, the proposal or transaction will

have to be modified or withdrawn.

Annual updates are required of all investigators participating in research that is subject to a management plan. Any investigator or inventor who has acquired a new or increased financial interest during the course of a research project or license agreement shall report it immediately. Annual updates and newly acquired interests are also reported using the Significant Financial Disclosure Form (Exhibit 1).

IV. Definitions

For purposes of this policy, the following definitions shall apply:

A. "Clinical Trial" means human subjects research whose purpose is to assess the safety or efficacy of drugs, devices, treatments, or preventive measures (including but not limited to Phase I, II, III, and IV FDA trials, preclinical trials, and trials utilizing normal human healthy volunteers) or which may have a substantial adverse effect on patients receiving care at a University health care facility.

B. "Conflict of Interest" means a divergence between an individual's financial interests and that individual's University obligations such that an independent observer might reasonably question whether the performance of the University obligations are adversely affected (or have the potential to be) by considerations of personal gain, and in the case of research, includes the existence of a significant financial interest of an investigator that could directly and significantly affect the design, conduct, or reporting of the research.

C. "Financial Interest" means any interest of economic or monetary value of an investigator/inventor and/or a member of that person's immediate family (spouse, parent, child, grandparent, grandchild, or sibling) that could reasonably appear to affect or to be affected by the particular research or technology transfer transaction under consideration including, but not limited to, the following:

1. **"Compensation"** means any interest paid during the preceding 12 months or reasonably anticipated in either the following 12 months or in any 12-month period during the research by a commercial or non-profit enterprise in exchange for personal services including but not limited to consulting fees, salaries, wages, retainers, honoraria (including, but not limited to, honoraria as defined by RCW 42.52.130 and referenced in the University's policy governing acceptance of honoraria, <http://www.washington.edu/faculty/facsenate/handbook/04-05-06.html>), and expense and travel reimbursements. Compensation does not include salary and other forms of non-royalty and non-equity compensation paid by the University or reasonable compensation paid by a public or nonprofit Entity in exchange for seminars, lectures or for service on advisory committees or peer review panels.

2. **"Equity"** means any interest in the profits of or other ownership interest in any commercial or non-profit enterprise, including common stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other convertible security.

3. **"Intellectual Property"** means any direct or indirect interest in a patent, trademark, copyright, trade secret, know-how or other intellectual property right, including but not limited to inventorship, ownership, royalties, and license fees paid during the preceding 12 months or reasonably anticipated in either the following 12 months or at any time during the research (regardless of whether such intellectual property right is owned by the University or an outside commercial or non-profit enterprise).

D. "Inventor" means any person, including a University Research Employee, who has created intellectual property in which the University has any right or interest, including but not limited to patents, copyrights, trademarks, trade secrets or know-how.

E. "Investigator" means any person, including a University Research Employee, responsible for the design, conduct, or reporting of research. It includes but is not limited to a principal investigator and a co-

principal investigator.

F. "Management Plan" means a written plan for the management, reduction or elimination of a potential Conflict of Interest relating to Research or a Technology Transfer Transaction arising from a Significant Financial Interest.

G. "Significant Financial Interest" (or "SFI") means any of the following:

1. For a Clinical Trial, any Financial Interest.
2. For Human Subjects Research other than a Clinical Trial (i) any Financial Interest exceeding \$5,000 in value, (ii) any Equity Interest; or (iii) any Intellectual Property Interest.
3. For all Research other than Human Subjects Research and all Technology Transfer Transactions, (i) any Financial Interest (including a Compensation Interest, an Equity Interest and an Intellectual Property Interest) exceeding \$10,000 in value, or (ii) any Equity Interest representing more than a 5% ownership in any single entity.

H. "University Research Employee" has the same meaning as set forth in RCW 45.52.010(21). For purpose of this policy, University Research Employee shall include:

1. Faculty employees with appointments in the professorial ranks (Professor, Associate Professor, Assistant Professor, Research Professor, Research Associate Professor, Research Assistant Professor) and, to the extent engaged in research and technology transfer, other faculty, librarians, and other academic personnel;
2. Research scientists and other University employees, including professional and classified staff, who have been specifically assigned to sponsored research projects and whose work contributes to the design or conduct of research or to the analysis or reporting of results; and
3. Other professional staff members who have been granted the right to apply for sponsored research projects by the Provost or by their respective Schools, Colleges, or Campuses.

V. Procedures

A. Identification of Persons Required to Disclose a Significant Financial Interest

1. Research. It shall be the responsibility of the principal Investigator of a Research project to identify all investigators who have a Significant Financial Interest requiring disclosure under this policy and to ensure that a Significant Financial Interest (SFI) Disclosure Form is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

2. Technology Transfer. It shall be the responsibility of UW TechTransfer to identify all inventors having a Significant Financial Interest requiring disclosure under this policy and to ensure that a Significant Financial Interest (SFI) Disclosure Form is prepared and submitted in accordance with this policy.

B. Submission of Significant Financial Interest (SFI) Disclosure Form. Every individual having a Significant Financial Interest requiring disclosure under this policy shall prepare a fully-completed SFI Disclosure Form that shall be submitted as follows:

1. Sponsored Research. All SFI Disclosure Forms relating to sponsored research or other research processed through Office of Sponsored Programs (OSP) shall be submitted to Office

of Sponsored Programs (OSP) by the Principal Investigator together with an appropriately completed Form eGC-1.

2. Non-Sponsored Research. All SFI Disclosure Forms relating to non-sponsored research or other research not processed through Office of Sponsored Programs shall be submitted directly to the Office of Research together with a transmittal memorandum describing the purpose of submission and the nature of the proposed research.

3. Technology Transfer. All SFI Disclosure Forms relating to Technology Transfer Transactions shall be submitted to UW TechTransfer.

C. Transmittal and Commencement of Review. SFI Disclosure Forms and accompanying confidential information will be forwarded to the Office of Research together with a transmittal memorandum. This memorandum should include the names of those disclosing a significant financial interest, the proposal or transaction title, the name of the research sponsor or prospective licensee, the OSP or UW TechTransfer office file number, any deadlines for completion of reviews; and any such additional information and documentation required to complete the review. Reviews will generally not be initiated until after the proposal has been funded or the transaction has been agreed upon in principle. Except in unusual circumstances, at least 30 days should be allowed for the completion of a review.

D. Standards for Approval. Proposed research and technology transfer activities will only be approved if the Office of Research determines that they can be conducted in compliance with federal, state, and University policies, laws, and regulations and if an adequate management plan can be implemented. When the research is sponsored solely by NSF and does not involve human subjects, the Office of Research may waive the requirement for a management plan if it determines that the risks of a potential conflict of interest are outweighed by the public interest in having the research go forward without a management plan.

E. Management Plan and Closing Letter. The Office of Research shall determine the terms, conditions and restrictions, if any, that are required as part of a management plan. It may consult with the investigator/inventor or other University employees as it deems appropriate when assessing a significant financial interest and developing a management plan. The management plan shall be conveyed in a closing letter with copies to involved Deans and Department Chairs, Office of Sponsored Programs, the Vice Provost responsible for academic human resources, and to other persons deemed appropriate, including the Director of the Human Subjects Division in the case of Human Subjects Research and the Vice President for Human Resources when professional staff are involved as investigators or inventors.. The management plan may require that one or more of the following actions be taken in order to manage, reduce, or eliminate a potential conflict of financial interest:

1. disclosure of Significant Financial Interests, including to the public, human subjects, researchers and other participants, publishers, and conference organizers;
2. monitoring of research by independent co-researchers and/or reviewers; disinterested individuals or committees;
3. placing copies of research data with a neutral party;
4. disqualification from participation in all or a portion of research or other activity affecting or affected by a technology transfer transaction;
5. requiring that the Significant Financial Interest be divested, restructured, or placed in blind trust;
6. modification or severance of relationships that create potential Conflicts of Interest;
7. changing terms of agreement relating to the research or technology transfer transaction;

8. reduction in University appointment;

9. requiring compliance with other University policies, such as those relating to conflict of interest, conflict of commitment, institutional conflict of interest, outside consulting, deeper involvement reviews, and use of human subjects in research;

10. requiring that Investigator participation in the recruitment or consent of subjects in human subjects research be prohibited or restricted;

11. requiring additional disclosures or actions with respect to matters before a human subjects review committee; and

12. requiring non-participation in any business transactions between the University and parties to agreements involving sponsored research or technology transfer transactions.

F. Summary Disposition Procedures. The Office of Research may implement summary procedures for the disposition of matters involving compliance with this policy that it deems reasonable and appropriate. These may include written approvals for annual reports, renewals, and no-cost extensions where Office of Research reasonably determines that the facts and circumstances pertaining to the matter being approved have not materially changed since the date of the original review and approval. All such summary approvals shall be documented and in writing.

G. Annual Reporting. All Investigators and Inventors who are subject to a management plan shall provide annual reports. In the case of sponsored research or unsponsored research involving human subjects these shall be provided to OSP. In the case of unsponsored research that does not involve human subjects and technology transfer licenses, these shall be provided directly to the Office of Research. Unless exempt as a summary disposition, annual reporting shall include submission of a new SFI Disclosure Form.

H. After-Acquired Significant Financial Interests. Any Investigator or Inventor who acquires a new or increased significant financial interest shall promptly submit a new SFI Disclosure Form. In the case of sponsored research or unsponsored research involving human subjects the form shall be provided to OSP. In the case of unsponsored research that does not involve human subjects and technology transfer licenses, these shall be provided directly to the Office of Research.

I. Sanctions and Remedies for Violation of Policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the Office of Research shall recommend appropriate sanctions consistent with University policies and procedures relating to faculty, employee, or other discipline. The Office of Research or UW TechTransfer may suspend an ongoing research project or technology transfer activity to prevent continued violation of this policy.

J. Record Retention. Records of and related to Significant Financial Interest disclosures shall be retained by the University no less than five (5) years after the termination or completion of the research or technology transfer transaction to which they relate.

K. Subcontractor Compliance. University subcontractors funded from HHS or NSF awards shall provide appropriate assurances to Office of Sponsored Programs that policies and procedures no less stringent than this policy exist and are enforced prior to submission of research proposals and execution of subcontracts. University officials shall take reasonable steps to confirm that all investigators employed by sub-grantees, contractors, subcontractors and collaborators participating in research are subject to conflict of interest rules and procedures that are no less stringent than this policy.

L. Federal Reporting. Office of Sponsored Programs shall be responsible for reporting disposition of matters involving disclosures of Significant Financial Interests in accordance with applicable federal requirements.

M. Auditing and Oversight Monitoring. Office of Research shall take such actions that it deems reasonable to audit and/or monitor compliance with Management Plans, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connection with Management Plans.

VI Guidelines

A. Participation in Business Negotiations. No University employee having a significant financial interest in a commercial or non-profit organization outside the University may participate in negotiating the terms and conditions of any agreement between the University and that organization.

B. Participation in Administration of Agreements. No University employee having a significant financial interest or a management position in a commercial or non-profit organization outside the University may have primary responsibility for administering an agreement between the University and that organization.

C. Availability of Research Data. All data and results arising from research in which an Investigator has a significant financial interest required to be disclosed under this policy must be available for disinterested scientific review.

D. Clinical Trial Investigators. No one may participate as an investigator in a clinical trial sponsored by a start-up commercial or non-profit organization in which he or she has an equity or intellectual property interest, holds a management position or serves on the organization's Board of Directors.

E. Outside Consulting Work. Investigators receiving compensation from a commercial or non-profit organization outside the University must ensure that no services performed as part of outside consulting work duplicate any work they perform while participating in research. Prior approval of all outside consulting is required. Approvals for faculty, librarians, and academic personnel are governed by the procedures expressed in the Outside Professional Work Policy (University Handbook, Volume 4, Part V, Chapter 6, <http://www.washington.edu/faculty/facsenate/handbook/04-05-06.html>). Approvals for professional or classified staff are governed by the Policy on Outside Consulting Activities and Part-time Employment by Professional or Classified Staff Employees (Administrative Policy Statement 42.3, <http://www.washington.edu/admin/rules/APS/47.03.html>).

F. Performance of University Obligations. Investigators receiving compensation from a commercial or non-profit organization outside the University must ensure that no services performed as part of outside consulting work are inconsistent with their University obligations.

G. Informed Consent. No investigator having a significant financial interest may participate in the informed consent process in research involving human subjects.

H. Disclosure of Interests. All investigators having a Significant Financial Interest must disclose the nature of the interest in connection with scholarly publication or presentation of the results of the research.

I. Financial Interests in Competitors and Competitive Products. Investigators shall be considered as having a financial interest for the purposes of this policy if they have any interest of economic or money value in a business that produces a competing product that could reasonably appear to affect or to be affected by the particular research or technology transfer transaction under consideration.

J. Clinical Trials of University Technology. No person shall participate in a Clinical Trial involving technologies licensed by the University if that person has a substantial equity interest in the licensee or intellectual property interest in the technology. When the University has either a substantial equity interest in the licensee or an intellectual property interest in the technology, funding for clinical trials will not be accepted without a full conflict of interest review and management plan being implemented.

K. Data Production and Analysis. Investigators having a Significant Financial Interest shall not perform

primary data analysis or production of data involving subjective scoring or similar methods of obtain data unless there is a clear and convincing indication that the design of the research and its analysis would provide no opportunity for bias.

L. Protection of Students. Particular attention shall be given to protecting students who could be adversely affected by the Significant Financial Interest of an investigator or other University employee who has academic responsibility for the student.

M. Oversight Arrangements. In general, oversight committees or other oversight arrangements will be established in cases involving intellectual property interests, equity interests in start-up companies, student researchers, and the potential for inappropriate use of state resources.

N. Conflicting Management Roles in Outside Organizations. No person may simultaneously serve in key management positions for both the University and an outside organization on the same research project. For purposes of this guideline, key management positions shall include principal investigator and any other role in which the person has the authority to make or recommend significant business, contractual, or financial decisions relating to the research project. In no event may an investigator act as Principal Investigator for both the University and an organization contracting with the University with respect to a research project unless another University employee, not in a direct reporting relationship to the conflicted University Investigator, has been designated by the University to be responsible for all business, contractual, and financial decisions relating to the outside organization.

VII. Other Relevant University Policies and Procedures

Additional University polices may be related to the management of Significant Financial Interests and may be referenced in any Management Plan developed under this policy:

- A. Employee Conflict of Interest
- B. Outside Professional Work
- C. Conflict of Commitment
- D. Deeper Involvement Reviews
- E. Policy Prohibiting Enrollment Incentives
- F. Use of Human Subjects
- G. Sponsored Research
- H. Patent, Invention, and Copyright Policy
- I. Institutional Conflict of Interest

Questions concerning this policy should be referred to the Office of Research at 543-7502.



Office of Sponsored Programs
4333 Brooklyn Ave NE | Box 359472
Seattle, WA 98195-9472 | (206) 543-4043 | Fax 685-1732 | [Contact Us](#)
Modified: September 10, 2008