

## POLICY

Effective Date: August 24, 2012

Approved By: President Bruce Shepard

Authority: [RCW 42.52](#); [42 CFR 50 subpart F](#); [45 CFR 94](#)

See Also: [PRO-U4520.06A](#) Reporting Financial Conflict of Interest by PHS- Funded Investigators  
[FRM-U4520.06A](#) Reporting Financial Conflict of Interest by PHS-Funded Investigators  
[POL-U5400.20](#) Financial Disclosure for Externally-Funded Projects  
[POL-U2100.01](#) Faculty Handbook

### **POL-U4520.06      REPORTING FINANCIAL CONFLICT OF INTEREST BY PUBLIC HEALTH SERVICES-FUNDED INVESTIGATORS**

***This policy applies to all Public Health Services (PHS)-funded investigators.***

#### **Definitions:**

**Public Health Services:** The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institute of Health (NIH) or as hereafter amended.

**Investigator:** The principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include investigators, graduate students, undergraduate students, collaborators, consultants, subcontractors, subgrantees, and subrecipients. Investigator includes spouse and dependent children. Spouse and dependent children as investigators applies only to financial disclosure and not training.

**Financial Interest:** Anything of monetary value or potential monetary value received from a non-University source that reasonably appears to be related to the individual's duties and responsibilities including, but not limited to payment from a non-university source, travel, stock, or intellectual property.

**Significant Financial Interest:** Any financial interests exceeding \$5,000 per year in value. This includes all sponsored or reimbursed travel regardless of the amount paid by any entity other than the University, the state, or the federal government.

**Financial Conflict of Interest:** A financial interest that could directly and significantly affect the design, conduct, or reporting of funded research, or the performance of duties and responsibilities performed on behalf of Western Washington University.

**Research Compliance Officer:** The Research Compliance Officer (RCO) works in Research and Sponsored Programs.

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**FCOI Committee:** Reviews financial conflicts of interest and then formulates a management plan. The committee consists of Research Compliance Officer, Assistant Attorney General, Risk Manager, and a faculty representative.

**Management Plan:** Taking an action to address a financial conflict of interest, which can include reducing, manage, or eliminating the financial conflict of interest, to ensure, to the extent possible, ensuring that the design, conduct, and reporting of research will be free from bias. The Management plan may also include a retrospective review and mitigation report, if necessary.

**Research Integrity Officer:** The Vice-Provost of Research is the Research Integrity Officer.

### 1. **Investigators Must Disclose Significant Financial Interests.**

All PHS sponsored investigators must disclose to the Research Compliance Officer (RCO) significant financial interests that may constitute a financial conflict of interest prior to the submission of a PHS sponsored proposal. PHS-sponsored investigators new to the University must disclose significant financial interests prior to disbursement of federal funds. Subsequent to the initial disclosure, investigators must submit updates annually by January 15. If the Investigator acquires a significant financial interest during the course of the year between annual disclosures, the Investigator must report it to the RCO within 30 calendar days.

### 2. **Office of Research and Sponsored Programs (RSP) is Responsible for Managing Financial Conflict of Interest Records for Public Health Services (PHS) Investigators**

### 3. **RSP Provides Mandatory Training to Public Health Services (PHS)-Sponsored Investigators**

RSP will provide mandatory financial conflict of interest training to all PHS sponsored investigators. Investigators must complete training prior to submission of a proposal for PHS funds or prior to the disbursements of funds for grants existing at the time of adoption of the policy. Investigators must repeat training:

- a) every four years;
- b) following a finding of noncompliance; or
- c) following the revision of the University financial conflict of interest policy.

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#### **4. Research and Sponsored Programs Reviews all Significant Financial Interest Reports**

The RCO conducts an initial review of all significant financial interest disclosures submitted by PHS investigators. The RCO determines whether the significant financial interest constitutes a financial conflict of interest with the Investigator's institutional responsibilities. If a financial Conflict of Interest exists, the RCO will refer the financial conflict of interest to the financial conflict of interest committee. The committee reviews the financial conflict of interest and creates a management plan to address the financial conflict of interest. The committee will also decide if an investigator is in non-compliance with the financial conflict of interest policy.

#### **5. Financial Conflict of Interest Determination Appeal Process**

Investigators may appeal the determination of the Financial Conflict of Interest Committee to the Research Integrity Officer within 30 calendar days of notice of the financial conflict of interest, the conflict management plan, or the determination of noncompliance.

#### **6. RSP Publishes Investigator Names and Financial Conflict of Interests and Reports them to the National Institute of Health (NIH)**

RSP will report all financial conflicts of interest to NIH within 60 calendar days of such discovery. Subsequently, RSP will report all financial conflicts of interest to NIH annually for the duration of the financial conflict of interest.

RSP reports all FCOIs on its website. The FCOI post includes the investigator's name, the source, and amount of the financial conflict of interest, as well as the management plan to NIH. RSP posts this information on the RSP website for the duration of the financial conflict of interest. RSP reports all incidents of bias found by the committee with the design, conduct, or reporting and a mitigation report will be issued addressing resolution of the financial conflict of interest. The RCO notifies NIH if any investigator fails to comply with the financial conflict of interest policy or management plan and the failure appears to have biased the design, conduct, or reporting of the NIH funded research. The appropriate body will take corrective action for the noncompliance.

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### 7. **RSP Will Maintain Records for Three Years**

RSP will maintain records of all financial conflict of interest-related documents for three years from the date the final expenditure report is submitted to the PHS and from other dates specified in 45 CFR 74.53(b) and 92.42.b, where applicable.

### 8. **Investigator Must Timely Complete Retrospective Review after the Committee Finds Noncompliance.**

Investigators must complete and document retrospective reviews within 120 calendar days of the Committee's determination of noncompliance for financial conflict of interest.

### 9. **RSP will Transfer Salary and Fringe Benefits if Investigator Fails to Comply with Financial Conflict of Interest Policy.**

RSP will transfer salary and fringe benefits to the budget of the department to which the Investigator is assigned if the Investigator fails to disclose significant financial interests or is in noncompliance with any requirement of this policy.