POL-POLICY

POLICY

Effective Date: August 24, 2012
Approved By: President Bruce Shepard
Authority: RCW 42.52; 42 CFR 50 subpart F and 45 CFR 94

See Also:
- POL-U5400.20 Financial Disclosure Policy for Externally-Funded Projects
- PRO-U4520.06A Reporting Financial Conflict of Interest by PHS-Funded Investigators
- 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 used in this policy:

Public Health Services: The Public Health Service (PHS) 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 Institutes 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. Spouses include same sex and different sex spouses/partners.

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

1 Spouse and dependent children as investigator applies only to financial disclosure and not training.
**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 (FCOI):** A financial interest that could directly and significantly affect the design, conduct, 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.

**Financial Conflict of Interest (FCOI) Committee** reviews financial conflicts of interest and then formulates a management plan. The committee consists of the 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 may include reducing, managing, or eliminating the financial conflict of interest, to ensure, to the extent possible, 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 a major revision of the University financial conflict of interest policy.

4. **RSP 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 FCOI 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 noncompliance with this financial conflict of interest policy.

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

   Investigators may appeal the determination of the FCOI Committee to the Research Integrity Officer within 30 calendar days of notice of the financial conflict of interest, the conflict management plan, or determination of noncompliance.
6. **RSP Publishes Investigator Names and Financial Conflicts 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 financial conflict of interest on its website. The financial conflict of interest 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 RSP website for the duration of the financial conflict of interest. RSP reports all incidents of bias found by FCOI Committee with the design, conduct, or reporting. 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 PHS-funded research. The appropriate body will take corrective action for the noncompliance.

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 45 CFR 92.42(b), where applicable.

8. **Investigator Must Timely Complete Retrospective Review After the FCOI Committee Finds Noncompliance.**

Investigators must complete and document retrospective reviews within 120 calendar days of the FCOI 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.