

Federal Financial Conflict of Interest in Research (FCOI) Policy

For William Paterson University of NJ research-based disclosures – Using Cayuse Outside Interests

1. Purpose

This policy ensures compliance with federal regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) regarding the disclosure and management of financial conflicts of interest (FCOI) in federally funded research. It promotes transparency and protects the integrity of research conducted at William Paterson University of NJ [WPUNJ].

This policy is established to ensure that investigators complete required financial disclosures at the time the proposal is submitted to a sponsoring agent and outlines when those financial disclosures are updated at award initiation and during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

2. Scope

This policy applies to all Investigators (including faculty, staff, students, and collaborators) who are responsible for the design, conduct, or reporting of research funded by federal agencies, including but not limited to NIH, NSF, and DOE. The intent of this policy is to emphasize transparency through timely disclosure of potential conflicts, ensuring research is free from bias due to financial interests, institutional management and reporting of conflicts to maintain public confidence in the integrity of research.

Cayuse Outside Interest module will be the reporting system used for obtaining, tracking and monitoring outside interest reporting, including training, for all individuals engaged in research at WP.

3. Definitions

Investigator: Any person responsible for the design, conduct, or reporting of research.

Significant Financial Interest (SFI): A financial interest exceeding \$5,000 or any equity interest in a non-publicly traded entity that could reasonably appear to be related to the Investigator's institutional responsibilities.

Financial Conflict of Interest (FCOI): An SFI that could directly and significantly affect the design, conduct, or reporting of federally funded research.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. As used in this policy, the term includes any such activity for which research funding is available from a federal awarding component through a grant or cooperative agreement or contract whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.

Research Compliance Officer (RCO): Role that ensures an organization's research activities adhere to all applicable laws, regulations, and institutional policies. They are responsible for reviewing conflicts of interest. Gladys Vega is currently serving as the institutional RCO until further notice.

4. Disclosure Requirements

Proposal-Related Disclosure: A Research-Based Disclosure (RBD) must be submitted for each new federal proposal and award.

Continuing Disclosure: All Investigators must submit an annual disclosure of outside interests via the Cayuse Outside Interests system for all active and ongoing federal awards.

Ongoing Disclosure: Updates must be submitted within 30 days of discovering or acquiring a new SFI. Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

While not all programs or funding announcements contain specific statements on the applicability of the FCOI regulations, agencies do provide award management guidelines and/or standalone conflict of interest policies on their website. It is important to review the sponsor guidelines for relevant FCOI requirements prior to submitting a proposal.

5. Review and Management

The Research Compliance Officer (RCO) or designee will review all disclosures. A financial conflict of interest exists when the institution's designated official(s) reasonably determines that an investigator's significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of the research. The institution is required to review each Investigator SFI disclosure to determine if an SFI:

- is related to the federally supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research), and
- could directly and significantly affect the design, conduct, or reporting of the federally funded research.

If an SFI is determined to be an FCOI, a Management Plan will be developed and implemented before funds are expended. Examples of management strategies include:

- public disclosure when presenting or publishing
- disclosure of FCOI to human research participants,
- monitoring of research by independent reviewers,
- modification of research plans,
- reduction/elimination of the SFIs (sale of an equity interest)
- severance of relationships that create SFIs,
- change of personnel responsibilities or
- disqualification from participation in all or a portion of the research.

6. Training

All Investigators must complete FCOI training in the CITI Program at <https://www.citiprogram.org>:

- Prior to engaging in federally funded research
- At least every four years
- Immediately if the policy changes or if an Investigator is found noncompliant
- An investigator is new to the institution

7. Reporting to Federal Agencies

FCOIs will be reported to the funding agency prior to expenditure of funds and within 60 days of identifying a new FCOI. Annual updates will be submitted for the duration of the project.

All PHS funded projects are reported using the eRA Commons FCOI Module. NSF funded projects are reported through the use of the Notifications and Requests module at [research.gov](https://www.research.gov).

Research funds and activities are held until the reports are submitted and accepted by the sponsor.

8. Record Retention

Records of all disclosures, reviews, and management plans will be retained for at least three years from the date of the final expenditure report.

9. Noncompliance

Noncompliance may result in:

- Restrictions on future submission of research proposals
- Retrospective review of research
- Corrective action plans
- Disciplinary action per university policy

All funded research activities require reporting noncompliance and/or corrective action plans directly to the sponsor for evaluation and assessment.

10. Use of Cayuse Outside Interests

All disclosures must be submitted through the Cayuse Outside Interests module. Investigators are responsible for maintaining accurate and up-to-date disclosures. The system supports both Annual and Research-Based disclosures.

Resources:

- [NIH COI resources page](#) – Public Health Service (PHS) regulation, which applies to grants and awards from any PHS agencies:
 - National Institutes of Health (NIH – including all individual Institutes and Centers)
 - Centers for Disease Control and Prevention (CDC)
 - Agency for Healthcare Research and Quality (AHRQ)
 - Food and Drug Administration (FDA)
 - Health Resources and Services Administration (HRSA)
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
- [NSF COI Policy](#) – National Science Foundation regulations for grants and awards
- [DOE Interim COI Policy](#) – Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance

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- [NASA COI Policy](#) (Grant Information Circular) – National Aeronautics and Space Administration regulations for grants and cooperative agreements

Frequently Asked Questions about PHS FCOI Regulations

General

Does everyone have to complete a disclosure?

The new regulation applies to all key personnel or Investigators, which includes the Project Director or Principal Investigator and any other individual who is responsible for the design, conduct, or reporting of research funded by the federal agency.

Are Postdocs and Graduate Students covered by the new regulation?

Yes, if the postdoc or graduate student meets the definition of an “Investigator,” which includes the Project Director or Principal Investigator and *any other individual* who is responsible for the design, conduct, or reporting of research funded by the PHS. Individuals who are purely advisory or are not sufficiently independent to be able to influence design, conduct or results of the research are not included.

Does the regulation apply to sub-awardees?

Yes, the regulations flow down to sub-awardees and subcontractors on PHS and NSF funded awards. Many institutions have certified their compliance through the Federal Demonstration Partnership (FDP) Institutional Clearinghouse. If a proposed sub-awardee is not registered on the FDP Clearinghouse, at proposal submission the sub-awardee must complete a mandatory Subrecipient Commitment form, available on the Office of Sponsored Programs (OSP) website. Additional forms may also be required, depending on whether the proposed sub-awardee already has its own conflict of interest policy in compliance with the regulations, or whether it commits to having such a policy before any subaward is made.

Do I need to take FCOI training?

All PHS and NSF Investigators must complete training on financial conflicts of interest and research prior to engaging in PHS or NSF funded research, and every four years thereafter. This includes any individual who is responsible for the design, conduct, or reporting of research funded by the PHS or NSF.

Are consultants required to file Financial Interest Reports?

No, provided that the consultant is serving in a purely advisory role or is not sufficiently independent to be able to influence design, conduct or results of the research. Any consultant listed as key personnel on a WP PHS-funded sponsored project is required to file a Financial Interest Report.

What is meant by “Conduct Research”?

To conduct research means to perform or otherwise participate in research, including:

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- Designing or directing research
- Enrolling research subjects (including obtaining informed consent)
- Making decisions related to eligibility or risks of participating
- Collecting, analyzing or reporting data
- Contributing to manuscripts for publication

Individuals who participate in any of these activities are required to file an annual Financial Interest Report.

When must I file a Financial Interest Report?

A project specific disclosure is required at the proposal preparation stage and prior to initiation of the project award.

When must I update my disclosure?

You must update your disclosure throughout the year whenever your financial interests change. PHS researchers must update their Financial Interest Report within 30 days of a new financial interest.

Q: What do I report or disclose?

A: You must disclose financial interests of any amount that are related to your institutional responsibilities, and that are held or received by you, your business if you have one, or your family.

Q: What is meant by Institutional Responsibilities?

A: The phrase “Institutional Responsibilities” is understood to mean all of the activities that you are required to perform in fulfilling your obligations to WP, including your sponsored activities (such as sponsored research or service projects), teaching, University administrative duties, clinical practice, and other University activities.

Q: What is meant by “related to institutional responsibilities”?

A: To understand what is meant by “related to your institutional responsibilities,” you should think about your outside activities that are associated with your area of professional expertise, or that are related to your role at the University. Ask yourself, “Am I being asked to participate in this outside activity because I am a professional in my field at William Paterson University?” If the answer is “Yes,” then it may reasonably appear that the requested activity is “related to your institutional responsibilities.” By this measure, any consultation in your area of professional expertise should be disclosed. You should use your

judgment when deciding what needs to be disclosed; but when in doubt, err on the side of transparency.

Q: What are Financial Interests that must be disclosed?

A: Financial Interests that must be disclosed include: Compensation/Remuneration, Equity Interests, Royalty Payments, Special Relationships, Sponsored Travel, Other Financial Interests (e.g., certain intellectual property rights).

Q: Must I disclose royalty payments?

A: You must disclose any payments to you or your family from intellectual property rights that reasonably appear to be related to your institutional responsibilities, such as royalties, license fees, or similar payments. Be sure to include royalty payments received either directly from an outside entity, which includes not-for-profit as well as for-profit entities, or through the University (such as through a University license agreement). PHS researchers must also include royalties or other income received from an independent publishing company arising out of authoring, editing or reviewing publications (print or electronic).

Do I need to report relationships with non-profit entities?

Yes. In a change from previous requirements, under the new regulation, Financial Interests now include remuneration from, and other relationships with, not-for-profit as well as for-profit entities.

Q: What counts as family for purposes of disclosure?

A: With regard to FCOI disclosure, your Family includes: Your spouse or domestic partner; your dependent children; your grown children, grandchildren, parents and grandparents (but only for those financial interests that are known to you); and any trust, organization or enterprise over which you, alone or together with your family, exercise a controlling or significant interest.

Q: Do I need to report travel?

A: If you are funded by the PHS or plan to apply for such funding, you must disclose all reimbursed or sponsored travel that reasonably appears to be related to your institutional responsibilities. You may report anticipated travel prospectively in your annual Financial Interest Report, to the extent it is known at the time. You must update your annual financial interest report within 30 days of any undisclosed sponsored travel. Your disclosure must include: the purpose of the travel, the identity of the sponsor or organizer, the duration of travel and approximate value.

Q: Must I report all sponsored travel, including that which is reimbursed through my sponsored project?

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A: No, you should not report travel that is funded through the University and charged to a sponsored project or through a departmental account, nor should you report travel that is reimbursed or sponsored by a Federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

Q: Can I project my future travel?

A: Any anticipated Sponsored Travel must be reported prospectively in your annual Financial Interest Report, to the extent it is known at the time. To the extent possible, listing all potential travel prospectively on your annual disclosure will reduce or eliminate the need to file updates throughout the year.

Q: What does the University do with my disclosure?

A: Your Financial Interest Reports remain in the confidential Cayuse system where access is restricted. The Office of Sponsored Programs reviews any reports that disclose financial interests related to your research. If a reported financial interest exceeds specific thresholds, it is considered a Significant Financial Interest and must be reviewed by additional WP administrative staff that manage risk and ethics.

Q: What is a Significant Financial Interest?

A: A Significant Financial Interest (SFI) is defined as any one of the following:

- Income greater than \$5,000 per year
- An equity stake in a public company greater than 5%, or with a value of more than \$5,000
- Any equity interest in a private company
- All royalties that exceed \$5,000 per year

Q: Will my disclosure be made public?

A: The information on your form is kept confidential, unless the FCOI reviewer determines that an FCOI relates to your PHS-funded research. Under the PHS regulation, the University is required to make accessible to the public information about Key Personnel's financial interests that are found to be conflicts of interest as defined by the regulations.

Q: How is an Investigator's FCOI made available to the public?

A: To meet the PHS requirement for public accessibility, the University will provide written information about FCOIs to members of the public who make a good faith written request. The request must specify the PHS Award and the researcher(s) in question. The University must respond within 5 business days of receipt of the request.