



# Financial Conflict of Interest Policy

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## Overview

No research or sponsored program activities occurring at Wheeling University shall be adversely affected by an Investigator’s financial interests. Investigators who apply to or receive research funding from government agencies must comply with both Wheeling University’s Conflicts of Interest policy and this more stringent federal Financial Conflict of Interest (FCOI) Policy which requires Investigators to disclose Significant Financial Interests (SFI), and institutions of higher education to identify, manage, and report potential Financial Conflicts of Interest. The existence of a SFI does not necessarily represent a Financial Conflict of Interest, but must be disclosed. Further, a Conflict of Interest is not prohibited in and of itself, but it must be managed appropriately and in accordance with the funder’s requirements and applicable regulations.

## Purpose

This policy fulfills the requirements of the Public Health Service (PHS) agencies, including the National Institutes of Health (NIH) with regard to Financial Conflicts of Interest. NIH requires recipient institutions and investigators to comply with the requirements of 42 CFR 50 Subpart F (grants and cooperative agreements) and 45 CFR Part 94 (contracts). The Public Health Service (PHS) regulations promote objectivity in research and provide a reasonable expectation to funders that the design, conduct, or reporting of research will be free from bias by any conflicting financial interest of an Investigator. If there are substantive differences between this policy and the regulations, the regulations shall take precedence.

## Scope

This policy applies to all Investigators at Wheeling University who apply for or receive research support from agencies of the Public Health Service (including NIH), and any other agencies who incorporate PHS regulations into their policies. Investigators are subject to funder-specific requirements, which may include mandatory training, disclosures and related updates, and reporting of foreign interests and travel reimbursed or sponsored by other organizations. This policy also applies to subrecipients on federal awards from these same agencies (see below). If a specific federal law, regulation, policy, or contract of a sponsor or prime awardee includes different requirements than this policy, the more stringent requirement applies.

## Definitions

Investigator: personnel responsible for the design, conduct, or reporting of research under the terms of a federal grant or contract, or the sub award to a federal grant or contract.

Institutional Official: the individual within Wheeling University responsible for the solicitation and review of disclosures of significant financial interest related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is the Controller or his or her designee.

Conflict of Interest Committee (COI Committee) is the university's committee or individual that advises the Institutional Official on Financial Conflict of Interest matters.

Financial Conflict of Interest (FCOI): exists when the Institutional Official (IO) reasonably determines that an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the funded research.

Significant Financial Interest (SFI): anything of monetary value related to the institutional responsibilities of an Investigator, which includes but is not limited to the following:

- remuneration received in the 12 months prior to disclosure that exceeds \$5,000 when aggregated;
- equity interest exceeding \$5,000;
- gains from intellectual property rights (e.g., patents, copyrights, royalties); or
- travel paid for or reimbursed by someone or entity other than a government agency, college or university, or academic medical institution.

“Significant Financial Interest” does not include:

- salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the Institution and agreements to share royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement accounts;
- income from seminars, lectures, teaching engagements review panels sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency.

Subrecipient: an entity that receives a sub award from the prime recipient and is accountable to the prime recipient for the use of the Federal funds provided by the sub award.

## Policy Statement

All Investigators who apply for or receive research funding from federal agencies with FCOI requirements must participate in required training, provide required disclosures, and participate in the management of any identified FCOIs; investigators will be informed of this policy, impose this policy on

subrecipients, retain records, and follow reporting requirements. The Institutional Official (IO) is responsible for ensuring implementation of this policy, reviewing disclosures to determine if an FCOI exists, and managing any potential conflict. The IO may suspend all relevant activities until they are satisfied that the potential FCOI is resolved or other appropriate action is implemented.

Training: Investigators with federal funding, including NIH, are required to complete the NIH FCOI Tutorial (<https://nexus.od.nih.gov/all/2018/12/03/new-financial-conflict-of-interest-training-module-available/>) and submit certification of successful completion to the Institutional Official (IO). Training must be renewed:

- at least every four years,
- as required by the funding agency or IO,
- in the event that this Policy is substantively amended affecting the requirements of Investigators,
- when an investigator is new to the institution, or
- if it is determined that the Investigator has not complied with this Policy or with a management plan related to their activities.

Disclosures: Each Investigator must disclose to the IO information requested, including SFIs, Sponsored Travel, and/or Foreign Interests, for themselves and their spouse, domestic partner, and/or dependent children. Disclosures must be current at the time of application for funding. At a minimum, forms must be completed:

- prior to proposal submission;
- annually for Investigators with active grants, commensurate with the funded project period;
- within 30 days of acquiring or discovering any new reportable significant financial interests; and/or
- within 30 days for Investigators joining the Institution.

Principal Investigators must ensure that required disclosures have been submitted by all other co-investigators and Senior/Key Personnel on their funded project. The Significant Financial Interest Disclosure Form is available from <https://wheeling.edu/academics/institutional-review-board/fcoi>.

Review: The IO or the IO's COI Committee will review and make an initial determination on all submitted Disclosures. A conflict of interest exists when the IO reasonably determines that a Significant Financial Interest could directly or indirectly affect the design, conduct, or reporting of funded research, teaching, or mentoring. If a potential FCOI is identified, the Investigator will be informed how the determination was made and the FCOI's relationship to the sponsored research will be documented and shared with the federal sponsor as required.

Management of FCOIs: If an FCOI is identified, the Institutional Official (IO) or designee will work with the Investigator to prepare and implement a written plan to manage the conflict and monitor ongoing compliance. Written plans are designed to:

- manage, reduce, or eliminate any Financial Conflict(s) of Interest;
- meet applicable legal requirements;
- facilitate the local resolution or management of any conflict; and
- protect the sensitivity of disclosed information.

Both the Investigator and the IO must approve the plan in writing before any related research begins or continues. Investigators must participate in and comply with any FCOI management plan, including any retrospective review, mitigation plan, and ongoing compliance monitoring.

Retrospective Review: If the IO determines that a Financial Conflict of Interest was not identified or managed in a timely manner, the IO or designee will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-

compliance was biased in the design, conduct or reporting of the research. This review may occur, for example, if an Investigator fails to disclose an SFI that is determined to be a FCOI, or an Investigator fails to comply with an FCOI management plan. The IO will submit or update any reports required by the funding agency.

Administrative Actions or Sanctions: Wheeling University reserves the right to impose sanctions on Investigators for failure to disclose SFIs or to abide by this Policy or related procedures.

Monitoring Subrecipients: Wheeling University is responsible for ensuring that all subrecipients are compliant with federal Financial Conflict of Interest regulations. The University will incorporate, as part of WU's FCOI Policy or its own. This agreement will address designated disclosure and reporting requirements that allow both WU and the subrecipient to be compliant with federal regulations.

Reporting: Wheeling University will endeavor to keep financial disclosures, management plans, and related information confidential to the extent permitted by law. However, federal regulations require that institutions report information about Investigators' potential and identified conflicts of interest to funding agencies and, in some cases, the public: reporting requirements vary by funding agency. The IO or designee will prepare and submit all reports in accordance with applicable regulations and/or official funding agency policy within the specified period(s) and as required, and notify the Investigator of such disclosures. Required reports may include, but are not limited to the following:

- the existence of real or potential conflicts of interest, and assurances that the COI has been managed, reduced, or eliminated
- initial and ongoing/annual FCOI reports to the funding agency as required
- information relating to any Investigator's disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI
- certain information concerning identified FCOI via a publicly accessible Web site or by a written response to any requestor, and updates to such information as specified

Public Accessibility: As Required by PHS, Wheeling University shall make this Policy available via a publicly accessible website at: <https://wheeling.edu/academics/institutional-review-board/fcoi>. The University will respond within five business days to any request for additional information concerning any Significant Financial Interests held by PHS senior/key personnel that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the senior/key personnel;
- A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information made publicly available shall be consistent with the requirements of the PHS policy.

Record Retention: Wheeling University will retain all financial disclosures, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the funding agency.

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