

WILKES UNIVERSITY CONFLICT OF INTEREST IN SPONSORED RESEARCH POLICY

These guidelines define Wilkes University's policy and procedures regarding conflicts of interest in relationship to sponsored projects and sponsored research. The guidelines are responsive to requirements of the National Science Foundation ([Section 510 of the Grant Policy Manual](#)) and the Public Health Service 2011 revised regulation on *Promoting Objectivity in Research* (42 CFR Part 50, Subpart F). They are intended to protect the credibility and integrity of the University's faculty and staff and to ensure compliance with Federal financial conflict of interest regulations.

Wilkes University has no interest in interfering with faculty and staff in their pursuit of legitimate outside interests. The University does, however, have a responsibility to manage, reduce or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator.

Definitions

A potential **conflict of interest** occurs when there is a divergence between a person's private interests and his or her professional obligations to Wilkes University such that an independent observer might reasonably question whether the person's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. For the purposes of this policy, a **financial conflict of interest** exists when the University, through procedures described herein, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of federally sponsored research or educational projects.

Investigator means any person who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by a federal sponsor. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Disclosure of Significant Financial Interests is the responsibility of all personnel responsible for the design, conduct, or reporting of research under the terms of a federal grant or contract (i.e, an "investigator" as defined above). Investigators must report their own significant financial interests and those of their spouses and dependent children.

Significant Financial Interest means one or more of the following interests, if it reasonably appears to be related to the Investigator's institutional responsibilities, including all research, teaching and/or service to the University: (Under the 1995 regulation, Investigators were only required to disclose their Significant Financial Interests related to their PHS-funded research.)

- a) With regard to any publicly traded entity, a **Significant Financial Interest** exists if the value of any remuneration received by the investigator or the investigator's spouse or dependant children from the entity in the twelve months preceding the disclosure *and* the value of any equity interest in the entity as of the date of the disclosure, when aggregated,

exceeds \$5000. Remuneration includes any salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- b) With regard to any non-publicly traded entity, a **Significant Financial Interest** exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5000, *or* when the Investigator (or spouse, or dependant children) owns *any* equity interest, regardless of dollar value.
- c) With regard to income related to intellectual property rights and interests, a **Significant Financial Interest** exists if income is received from any entity other than Wilkes University; intellectual property income from Wilkes would result from agreements to share in royalties related to intellectual property rights.
- d) With regard to reimbursed travel or sponsored travel related to an investigator's institutional responsibilities, a **Significant Financial Interest** exists if the sponsor is not a federal, state, or local government agency, an institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Investigator must disclose the purpose of trip, identity of sponsor, destination, and duration. Even if the investigator does not know the exact amount of sponsored travel (because it was paid on investigator's behalf rather than reimbursed), the occurrence of sponsored travel must still be reported. If disclosure of exact amount of sponsored travel is critical to determining whether a financial conflict of interest has occurred, Wilkes University has the right to request and receive such information.

The term **Significant Financial Interest** does not include:

1. Salary, royalties, or other remuneration from Wilkes University;
2. Income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator (or spouse, partner, or dependant children) does not directly control the investment decisions made in these vehicles; or
3. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
4. Income from service on advisory committees or review panels a federal, state, or local government agency, an institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Disclosure

1. Each Investigator who has a **Significant Financial Interest** requiring disclosure shall complete a **Significant Financial Interests Disclosure Form**. The completed Disclosure Form must be submitted in a sealed envelope to the office of the Director of Sponsored Programs at the time a proposal is submitted. This disclosure information will be forwarded to the Vice President for Finance for review.
2. In addition, Investigators must update those financial disclosures a) within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new

Significant Financial Interest and b) annually within the period of an award, beginning with the anniversary date of the original disclosure.

Review Process

The Wilkes University Vice President of Finance shall review all **Significant Financial Disclosures** to determine whether a financial conflict of interest exists and to determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict of interest. Depending on the scope of the potential conflict, the Vice President may convene the Conflict Review Committee (CRC) to assist in timely review. Members of the CRC will include the Vice President of Finance, the Director of Sponsored Programs and Grant Support, and the Dean of the College or School where the individual under review holds a position. If the individual under review is a Dean, the Provost will appoint the third committee member.

If a determination is made that a significant conflict of interest constitutes a **Financial Conflict of Interest**, the CRC will be convened to review the research, the financial interests in question, and the areas of conflict in order to devise a plan for the management of the Financial Conflict of Interest. The management plan may include conditions or restrictions to manage, reduce, or eliminate **Financial Conflicts of Interest**, which may include, but are not limited to, the following:

1. Monitoring of research by independent reviewers;
2. Modification of the research plan;
3. Disqualification from participation in the portion of the federally funded research that would be affected by **Significant Financial Interests**;
4. Divestiture of **Significant Financial Interests**;
5. Severance of relationships that create actual or potential conflicts;
6. Public disclosure of Financial Conflicts of Interest.

The Investigator will be consulted as to the implementation of the Management Plan; the Investigator must agree to the Plan before the research can proceed. If the COI Committee and the Investigator cannot agree upon a Management Plan, the relevant regulatory bodies and funding agencies will be notified.

The Vice President for Finance and Support Operations will notify the Provost of the conditions or restrictions to be imposed. If the Provost determines that imposing the above referenced conditions or restrictions would be ineffective or inequitable, or that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Provost may recommend that, to the extent permitted by Federal regulations [PHS policy, for example, does not permit such an action], the research go forward without imposing such conditions or restrictions. The Provost may also consider faculty appeals to Conflict Review Committee's decision(s). The Provost shall make the final decision regarding any resolutions that may be required regarding a proposed condition or restriction.

Reporting Financial Conflicts of Interest

1. **Sponsoring Agency:** Significant Financial Interests that are determined to be **Financial**

Conflicts of Interest will be reported to the sponsoring agency in accordance with its requirements within 60 days of the original disclosure.

2. **Public Request:** As required by sponsoring agency regulations, information on the nature of such Conflicts of Interest will be made available to the members of the public by the Vice President and General Counsel in response to inquiries specifying the Investigator name and the research project in question within 5 business days of receipt of such requests.
3. **University Reporting:** The Vice President of Finance will also compile regular reports to the Wilkes University Board of Trustees for review and oversight.

Violations of Conflict of Interest Policy

Whenever an Investigator has violated this policy or the terms of any ~~resolution~~ management plan required by the Conflict Review Committee (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms) the Vice President of Finance shall notify the Provost, who will impose sanctions or institute disciplinary proceedings against the violating individual.

If the violation results in a collateral proceeding under College policies regarding research misconduct, then the Provost will defer decision on sanctions until the misconduct process is completed.

In addition, the University shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

Record Maintenance

Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Vice President for Finance Office until 3 years after the letter of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

Training

Investigators on NIH/PHS-funded project: each investigator (including senior key personnel) on projects funded by NIH or other Public Health Service (PHS)-affiliated agencies must complete training in the University's most current conflict of interest policy prior to engaging in research related to NIH/PHS award. Training must be taken at least once every four years. Training procedure will be provided by the Office of Sponsored Programs and Grant Support.

1. **New or Previously Unfunded Investigators:** New and/or previously unfunded Investigators who notify the Office of Sponsored Programs and Grant Support of their intent to submit a research proposal to NIH or another PHS-affiliated agency will be required to complete training prior to submission of their proposal. Training procedure will be provided by the Office of Sponsored Programs and Grant Support.
2. **Investigators on non-NIH/PHS projects:** For Investigators sponsored by or seeking funding from NSF and/or other federal agencies, as well as any Investigators initiating

research sponsored by a private, for-profit entity, the above training activities are optional but strongly recommended.

Collaborative Projects/Subrecipients

The University is responsible for ensuring that all subrecipients are compliant with the applicable federal regulations regarding **Financial Conflicts of Interest**. To this end, the University shall enter a written agreement with each subrecipient that shall specify whether this policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient Investigators. Said agreement will specify the timing for reporting of **Financial Conflicts of Interest** by subrecipients to Wilkes University to enable timely review and reporting of such **conflicts** in compliance with funding agency requirements.