

Policy Number
6110
Date Created/Revised
02/01/2020
Executive Responsibility
[Vice Provost-Research
Provost](#)
Functional Responsibility
[Research Compliance](#)
Former Wright Way Policy
1107

6110.1 Introduction

The purpose of the policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial conflicts of interest.

This policy establishes guidelines to assist investigators in managing external professional activities or relationships so as not to interfere with their primary duties to the university nor compromise the educational interests of university students with whom they work.

It is not the intent of this policy to eliminate or prohibit all situations involving potential conflicts of interest. Rather, the policy is intended to enable investigators to recognize situations that may pose a financial conflict of interest, to provide a process for disclosing these situations to the university and for working with the Office of the Vice Provost for Research (OVPRG) to manage these situations.

The university believes that with clear guidelines and principles, and with appropriate supervision and monitoring, it is possible for interaction between outside entities and the university to take place in a manner that prevents real or perceived bias.

6110.2 Applicability

This policy applies to all faculty, staff and students at the university.

Specific guidance and requirements regarding Public Health Service (PHS)-funded research are noted in this document (or provided in Appendix A).

6110.3 Definitions

1. **Investigator** means the project director/principal investigator and any other person, whether faculty, staff, or student and regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposal for funding, including persons who are subcontractors, collaborators, or consultants.

Financial Interest means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children.

Management Plan means a written plan developed to manage conflicts by eliminating or reducing the Financial Conflict of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.

Significant Financial Interest means, except as otherwise specified in this definition:

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. With regard to any 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 and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement). Equity Interests 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 \$5,000, or the Investigator (or the investigator's spouse or dependent children) holds any equity interest.
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. For PHS-funded investigators, any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities.
3. The term *significant financial interest* **does not** include the following types of financial interests:
 - a. Salary, royalties, or other remuneration paid by the university to the investigator if the investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;
 - b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency within the United States, 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;

- c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;
- d. Income from service on advisory committees or review panels for a federal, state or local government agency within the United States, 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 high education.
- e. For PHS-funded investigators, travel that is reimbursed or sponsored by a federal, state, or local government agency within the United States, 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.

Institutional Responsibilities means an investigator's professional responsibilities on behalf of the university including research, consultation, teaching, professional practice, and service.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge. It includes basic and applied research and product development. It includes activities sponsored through a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

6110.4 Financial Conflict of Interest

A financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research. Examples include, but are not limited to, the following:

1. Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity that has an interest in the investigator's university-based research;
2. Using students or employees of the university to perform services for an outside entity in which an investigator (and/or investigator's spouse and/or dependent children) has an ownership interest for from which he/she receives any remuneration;
3. Investigator (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research;
4. Investigator (and/or an investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research;
5. Serving as an officer, director, or in any other fiduciary role for an outside entity that is financially interested in the investigator's university-based research, whether or not remuneration is received for such service.

This policy addresses individual financial conflicts of interest; however, the university may also have conflicts of interest in research whenever the financial interests of the university, or of a university official acting within his or her authority on behalf of the university, might affect—or reasonably appear to affect—university processes for the conduct, review, or oversight of

research. If institutional conflicts of interest are identified via the disclosure process described below, they will normally be addressed in a manner that is consistent with this policy.

6110.5 Investigator Responsibilities

Investigators are responsible for the following:

1. Reading and understanding this policy;
2. Disclosing significant financial interests to the university by completing appropriate forms on or before a specified date or before submission of the grant/contract application;
3. Completing any training in a timely manner as required by the sponsor or university;
4. Updating disclosure statements as changes occur, so that the statement on file is current and accurate at all times when an award is pending or in force; and
5. Complying with any and all Management Plan provisions and monitoring requirements, as applicable.

6110.6 Disclosure

Each year an investigator must disclose in writing all significant financial interests (SFIs) that are relevant to an investigator's institutional research responsibilities or within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has been eliminated.

Investigators are required to complete the annual disclosure form even if they have no financial interest to report. Transactional disclosure is also required at the time a research proposal is submitted to the Office of Research and Sponsored Programs and when a protocol is submitted to an external Institutional Review Board (IRB), the university's IRB or the university's Institutional Animal Care and Use Committee (IACUC).

For PHS-funded investigators, any reimbursable or sponsored travel, as required by the sponsor, must be disclosed. The disclosure must include: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The university will review this disclosure and determine whether further information is needed to ascertain whether travel constitutes an FCOI with PHS-funded research. Disclosure of travel must occur no more than 30 days after the last day of the trip.

6110.7 Review

The (OVPRG) conducts an initial review of all disclosures. If necessary, the OVPRG obtains additional information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. Barring unforeseen circumstances, the process of information collection and review will be carried out in an expeditious manner. The OVPRG then formally identifies activities that require further review and refers such cases to the Outside Interest Committee (OIC).

The OIC will review the collected information to determine whether a financial conflict of interest exists by considering the following:

- Impact on integrity of research data;
- Risks to rights and safety of animal and/or human research subjects;
- Risks to the rights of students and trainees participating in research; and
- Appearance of conflict of interest.

If a financial conflict of interest is identified, the OIC will determine whether the research can be undertaken with appropriate university management.

6110.8 Outside Interest Committee

The OCI is a small standing university committee that works with investigators and the OVPRG to resolve potential or apparent financial conflicts of interest by implementing reasonable controls. It also provides oversight for the implementation of this policy and makes recommendations for all future modifications.

The "core" committee will be composed of a minimum of three faculty members and the OVPRG designee. The OVPRG will appoint faculty members who have active research or substantial research experience and are representative of campus departments. Ad hoc members with subject matter expertise may be appointed by the OVPRG, as needed. Ex-officio membership may include representatives from the Office of General Counsel, the Office of Technology Transfer, the Institutional Review Board (IRB), and the Institutional Animal Care and Use Committee (IACUC), when appropriate.

In addition to this policy, OIC actions shall be in accordance with formal administrative procedures that are typically reviewed and approved by the provost in consultation with the Faculty Senate. However, any revision to this policy that affects the terms and conditions of employment of Bargaining Unit Faculty requires instead the approval of the university and of AAUP-WSU. All such revisions become effective upon their receiving the required approvals.

6110.9 Management

Management means to take action to address a financial conflict of interest, which includes reducing or eliminating the financial conflict of interest, to ensure that the design, conduct or reporting of research is free from bias or the appearance of bias. Typically, written Management Plans are developed according to the nature of the conflict of interest and of the sponsored research, and whether the investigator is conducting bench, animal or human subject research. The OIC will work with the OVPRG, the investigator, and the investigator's supervisor to resolve potential or apparent financial conflicts of interest and finalize the Management Plan. The final formal Management Plan will be signed by the investigator, the investigator's supervisor, and the OVPRG.

These plans will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include:

1. Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate to the discipline;
2. Disclosure of significant financial interests directly to participants involved in human research;
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
4. Modification of research plan;
5. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
7. Severance of relationships that create the actual or potential conflict of interest;
8. If it proves impossible to reach an acceptable Management Plan, funds will be returned to the sponsor.

Boilerplate Management Plan language will be made available on a publicly accessible website. The investigator, his/her chair and the appropriate dean or senior official will be given a copy of the final Management Plan. Any questions or concerns about the Management Plan should be forwarded to the OIC for consideration.

6110.10 Monitoring

Investigator compliance with Management Plans will be regularly monitored by the university to assure compliance and provide appropriate institutional oversight. The frequency of monitoring will be dictated by sponsor requirements, as well as Management Plan provisions.

6110.11 Vulnerable Populations

Human Subject Research - Special precautions must be taken to protect human subjects who participate in university research. The IRB must review and approve any Management Plan for human subject research to proceed.

Students and Trainees - Students and trainees, hereafter referred to as "students," may perform research related to an investigator-owned company only through a written sponsored research agreement or formal internship agreement through the university. Such agreements shall not limit a student's normal right to intellectual property and research data, allow for inappropriate publications delays, or hinder the normal progress of attainment of the applicable degree.

Special provisions for students employed by a company or outside entity where an investigator has a financial interest will be specifically called out in the investigator's Management Plan.

6110.12 Appeal

If an investigator wishes to appeal the Management Plan, an appeal may be made to the OIC within 10 business days of receipt of the final plan. Should the investigator not file a written appeal with the OIC by such time, then the investigator shall be considered to have waived his/her right to appeal that and the determination of the OIC shall be final. If the investigator's appeal is denied by the OIC, then he/she may make a subsequent appeal to the provost. The provost shall notify the investigator within 10 days as to whether the appeal is granted or denied. During the pendency of any appeal to the OIC or Provost, the investigator must either (a) agree to abide by the initial recommendations of the OIC; or (b) remove himself/herself from the research; or (c) not expend any funds under any award from a sponsor for the conduct of the research at issue. The Provost's decision will be final.

6110.13 Record Retention

The university will maintain records of all financial disclosures and all actions taken by the university with respect to each financial conflict of interest for at least three years after the termination or completion of the award, and in the case of federally funded research, at least three years from the date of submission of the final expenditures report.

6110.14 Regulatory and Legal Obligations

Investigators should be aware that as a result of their financial interest or fiduciary role in an outside entity/company they may have additional obligations under various state and federal laws, in addition to this policy. These laws include, but are not limited to, the following:

State

1. Ohio Revised Code (Sections 102.03, 2921.42 and 2921.43)

Federal

1. Public Health Service (PHS) 42 CFR, part 50, subpart F and 45 CFR part 94
2. National Science Foundation (NSF) Grantee Conflict of Interest Policies
3. U.S. Food and Drug Administration (FDA) 21 CFR 54
4. Federal Office of Management & Budget publication 2 CFR Chapter I, Chapter II, Part 200, et al., "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."
5. Securities and Exchange Commission (SEC)

Investigators should also be aware that research sponsors may have additional requirements regarding financial interests that would be defined in the grant or contract.

6110.15 Confidentiality

All information related to the review and management of financial interests is strictly confidential. The information is only made available to the persons within the university

charged with the review of an individual case, including the appropriate dean or administrative official. The university also must release information related to financial conflicts of interest and their management to the sponsor, as required by the sponsor's regulations or policies.

6110.16 Enforcement

Possible violations of this policy include, but are not limited to, the following:

1. Intentionally or recklessly providing incomplete, false, or misleading information on the disclosure form;
2. Failing to make required disclosures; or
3. Failing to provide information requested by the university to adequately review a financial interest and/or manage an identified conflict of interest.

The university may take appropriate disciplinary action against covered individuals who violate this policy. This disciplinary action may include, but not be limited to:

1. Written reprimand
2. Suspension
3. Non-renewal of appointment
4. Involuntary termination of employment

Disciplinary action under this policy for non-bargaining unit faculty shall be consistent with and subject to applicable provisions of the university's Human Resources Policies or applicable sections of the Faculty Handbook. For bargaining unit faculty, any disciplinary action shall be consistent with and subject to applicable sections of the Collective Bargaining Agreement between AAUP-WSU and the university.

6110.17 Policy Revisions

Any revision of this policy requires the approval of the President, Provost and the Faculty Senate. However, any revision of this policy that affects the terms and conditions of employment of Bargaining Unit Faculty requires instead the approval of the university and AAUP-WSU. All such revisions become effective upon their receiving the required approvals.

6110.18 APPENDIX A Public Health Service (PHS) Research Reporting Requirements

Prior to expenditure of any funds or within 60 calendar days for any interest that the university identifies as conflicting subsequent to the university's initial report under a PHS-funded research project, the university must provide the PHS Awarding Component with a Financial Conflict of Interest (FCOI) report regarding the related FCOI and implemented Management Plan. This report must include the following information:

- Grant/Contract Number
- Project Director/Principal Investigator (PD/PI) or contact PD/PI
- Name of investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, or honoraria)
- Value of the financial interest
- Description of how FCOI relates to PHS-funded research
- Key elements of the Management Plan

Annual updates are also required for the duration of the research project.

- Status of the FCOI
- Changes to the management plan

If a significant financial interest (SFI) is not disclosed or reviewed in a timely manner, the university must review the SFI, determine if it is related to PHS-funded research; determine whether a financial conflict of interest exists, and, if so:

- Implement a Management Plan for ongoing research; and
- Complete a retrospective review of investigator's activities and the PHS-funded research project within 120 days of a non-compliance finding to determine if there was bias in the design, conduct, or reporting of such research; and
- If bias is found, notify the PHS Awarding Component promptly by submitting a mitigation report.

Public Disclosure

In accordance with PHS regulations, the university will respond to requests regarding financial conflicts of interest by written response within five business days of a request. The response shall include, the investigator's name, position relative to the research project, the name of the entity in which the SFI is held, nature of the SFI, approximate dollar value of SFI, or a statement that the value cannot be readily determined.

Subrecipients

For PHS research that involves subcontractors, subgrantees or subawardees (collectively "subrecipients") at other institutions, the university requires written agreement terms from subrecipients that they have a conflict of interest policy that conforms to the requirements of all applicable regulations, including time periods to meet disclosure and/or financial conflict of interest (FCOI) reporting requirements.

If any subrecipient does not have such a conflict of interest policy, then the university shall require that Subrecipient follow the university's (WSU'S) policy, and Subrecipient's failure to promptly do so upon request from the university shall be considered to be grounds for immediate termination by the university of any applicable subcontract or subaward. Any written agreement terms required by the university shall contain the provision that subrecipients will report to the

university as the awardee institution, any identified FCOI in sufficient time to allow the university to report the FCOI to meet reporting obligations described above.

Required Training for Investigators

Investigators must complete the university's FCOI training requirements prior to engaging in research related to the PHS-funded grant or contract and at least every four years, and immediately under the designated circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to the university
- The university finds that an investigator is noncompliant with this policy or their university-approved management plan.