

Outside Interest Committee Procedures for Reviewing Significant Financial Interests Related to Research

I. Purpose

The purpose of these procedures is to provide additional guidance and clarification regarding the process of reviewing disclosures of significant financial interests held by Wright State University (WSU) faculty, staff and students by the Office of the Vice President for Research (OVPR) and the Outside Interest Committee (OIC) in accordance with WSU's "[Research Conflict of Interest and Financial Disclosure Policy](#)." It also describes procedures on how to manage those significant financial interests found to be in conflict, how to create appropriate management plans and how to monitor ongoing financial conflicts of interest. The intent of these procedures is to protect the integrity and credibility of WSU and its faculty, staff and students, to enhance the protection of human subjects in research, and to maintain compliance with federal regulations.

II. Definitions

A. Outside Interest Committee

A small university committee that works with investigators and the OVPR to resolve potential or apparent financial conflicts of interest by implementing reasonable controls through management plans and by drafting appropriate policies and procedures to facilitate transparency.

B. Fiduciary Role

A fiduciary role refers to a legal and/or ethical obligation on the part of a covered party to act in the best interests (i.e., the financial and operational success) of another. Examples include, but are not limited to, a management role in a company or membership on a board of directors.

C. Entity

Entity means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (or domestic partner or dependent) receives remuneration or in which any person has and ownership or equity interest.

D. Investigator

The project director/principal investigator and any other person 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.

E. 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 or related royalties and interests (e.g., patents, copyrights), upon receipt of any 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 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;
 - b. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local agency, an Institution of higher education, an

academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

- c. Income from service on advisory committees or review panels for a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- d. For PHS-funded investigators, travel that is reimbursed or 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 that is affiliated with an Institution of higher education.

F. Financial Conflict of Interest

A financial conflict of interest means a significant financial interest that is related to a research program or project and could directly and significantly affect the design, conduct or reporting of that research.

G. Institutional Responsibilities

This means an Investigator's professional responsibilities on behalf of the University including, research, consultation, teaching, professional practice, and service.

H. Disclosure

This means an Investigator's written disclosure of significant financial interest to Wright State University and in presentations, publications, and consent forms.

I. Reporting

Wright State University's reporting of a financial conflict of interest to a PHS awarding component or other sponsor.

J. Monitoring

Monitoring management plans includes requiring written updates from the Investigator, examining study records, and reviewing publications, presentations (slides), and consent forms for disclosure language. WSU must monitor compliance with management plans on an ongoing basis until the completion of the affected research project.

III. Authority

The OVPR and the OIC is empowered by the WSU "Research Conflict of Interest and Financial Disclosure Policy" to:

- Oversee the disclosure process for Investigators;

- Review annual disclosure forms in which significant financial interests have been identified, determine whether a real or perceived financial conflict of interest exists, and develop management plans for those financial conflicts of interest that cannot be eliminated;
- Consult with appropriate deans, department chairs, supervisors and administrative officials in the development of such plans;
- Coordinate with the Institutional Review Board(s) to identify and address real or apparent financial conflicts of interest arising in human subjects research;
- Review and approve school/unit conflict of interest guidelines;
- Help conduct and support education of faculty, staff, and students on financial conflicts of interest issues; and
- Collect aggregate data for the university regarding financial conflicts of interest and provide that data to the Provost for compliance oversight purposes.

The OVPR designee and OIC are also authorized to collect sufficient information to allow it to identify the existence and extent of a real or apparent financial conflicts of interest and the feasibility of options for managing, reducing, or eliminating such a conflict.

IV. Outside Interest Committee

The “core” committee will be composed of three faculty members of the university’s research faculty and the OVPR designee. Ad hoc members with subject matter expertise may be appointed by the OVPR, 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.

The OVPR will appoint a Chairperson and a Co-Chairperson to lead the meetings of OIC.

Normally, the OVPR designee will act as Chairperson and a voting faculty member as the Co-Chairperson.

V. OVPR Responsibilities

The OVPR is responsible for administering the financial conflict of interest (FCOI) process at the university. The OVPR designee and appointed administrative staff will:

- Track significant financial interest (SFI) disclosure information, and provide data on compliance to the OIC and the OVPR.
- Consult with Investigators and with members of the OIC, as needed, in drafting management plans.
- Document OVPR designee and OIC review (meeting minutes) of management plans and provide written communication to Investigators, as appropriate.

- Monitor management plans periodically to review compliance with and the need for alteration of the management plan.
- Provide administrative support to the OIC by scheduling meetings and distributing review materials in a timely manner.
- Develop and implement mechanisms for communicating to faculty, staff and students. policy and procedure changes as they relate to FCOI, including a university web page.
- Provide FCOI education and training programs for faculty, staff and students.
- Retain records in accordance with federal regulations and sponsor requirements.

VI. OIC Meetings

The Outside Interest Committee (OIC) normally meets monthly throughout the academic year unless a meeting is cancelled by the Chair for good cause (i.e., lack of quorum or business).

Minutes of each meeting shall be drafted by a member of the OVPR. Members of the OIC will be provided with the minutes of the last meeting in advance of the next meeting and the minutes will be ratified via a vote of the committee. Meeting packets will be distributed to members at least one week prior to the meeting.

The OIC will manage, reduce, or eliminate financial conflicts of interest under its purview in an efficient and amenable manner. It will seek consensus in its decisions; however, if this cannot be obtained, the appropriate course of action to be taken will be determined by a vote of the simple majority of those attending the meeting.

A quorum, which shall consist of a simple majority, is necessary to conduct the business of the OIC. In the absence of a quorum, the voting members present at a meeting may review disclosures and recommend OIC action, but it must be subsequently ratified by a majority of the OIC members prior to taking effect. OIC member ratification may take place electronically once all members are given the opportunity to review the meeting minutes. The action of a quorum of the voting OIC members electronically on an agenda item shall constitute official OIC action on a proposed agenda item. Each voting OIC member will have one vote. Voting will proceed after an opportunity for full discussion and debate has been afforded.

The OIC will use its best efforts to reach a final determination as to any real or potential financial conflict of interest referred to them in a timely manner.

VII. Annual and Research-Based Disclosure Process

Federal regulations and university policy require that all persons who are involved in the design, conduct, or reporting of research, hereafter, referred to as the “Investigator,” must annually disclose any and all significant financial interests that are related or appear to be related to their

institutional responsibilities. The following list of individuals would be considered university “Investigators:”

- All regular faculty engaged in any research activities;
- All part-time, clinical, research, auxiliary or emeritus faculty who have a role in the design, conduct, or reporting of research – including research with animals and human subjects;
- Clinical and research staff members and students who have a role in the design, conduct, or reporting of research with animals or human subjects. Examples of such roles include the following:
 - a. Staff or students who are formally listed on, or their salary or effort is associated with, a specific sponsored project or award;
 - b. Staff and students who are included as a co-investigator or key personnel on an Institutional Review Board (IRB) or Laboratory Animal Care and Use Committee (LACUC) application;
 - c. Clinical or research staff or students who collect or analyze data, or consent research subjects; and
 - d. Staff or students who plan to participate as authors on publications or presentations resulting from research.
- Principal administrative officials designated by the OVPR as having a significant role in the supervision of research.

The university, not the Investigator, is responsible for determining if any of the disclosed SFIs are related or appear to be related to research conducted at WSU. Investigators are required to complete disclosure form(s) even if they have no financial interests to report. Each year the OVPR will inform Investigators of the deadline to disclose and provide access to the appropriate disclosure forms via electronic submission. Research proposals involving Investigators who have not submitted an annual disclosure form prior to the deadline or who have submitted an incomplete form, will be held until receipt of the disclosure form(s) by the OVPR.

Research-based disclosure is also required at the time a research proposal is submitted to the Office of Research and Sponsored Programs and when a non-exempt 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). Research-based disclosure questions are utilized to confirm that there are no SFIs related to the proposal or proposed research study. Positive research-based disclosures will be forwarded to the OVPR and handled in accordance with the process described above.

Investigators who conduct PHS-funded research (see attached “Sponsored and Reimbursed Travel Procedures”) must also disclose any reimbursable or sponsored travel that is not reimbursed or 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 that is affiliated with an Institution of higher education. Investigators will be asked to provide the

following information: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. The university will review this disclosure and determine whether further information is needed to determine whether travel constitutes an FCOI with PHS-funded research.

VIII. Individual Conflict of Interest Review

Designated members of the OVPR will conduct an initial review of all disclosures to determine: (1) that all Investigators have submitted a disclosure form, and (2) which disclosures require additional follow up. When appropriate, they will obtain additional information from the Investigator and other individuals to help the OIC 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.

IX. Management Plans

“Management” means to take action to address a financial conflict of interest (FCOI), 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 and must include the following:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator’s agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Examples of conditions or restrictions that may be employed to manage conflicts include:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate to the discipline;
- Disclosure of significant financial interests directly to participants involved in human research;

- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- Modification of research plan;
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create the actual or potential conflict of interest.

Normally, an Investigator will be provided with a draft of the management plan to review and comment before it is finalized.

X. Institutional Conflict of Interest Review

Institutional financial conflicts of interest (FCOI) arise 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. In such cases, it may be necessary to develop an institutional management plan.

Most often an institutional FCOI accompanies individual conflicts of interest on the part of an Investigator. However, it is possible that there could be an institutional FCOI in the absence of an individual FCOI. For example, if a company sponsors research at WSU, where WSU has a financial interest in the company, but none of the WSU Investigators have a financial interest in the company, only an institutional FCOI would exist.

In this instance, an institutional management plan would be developed for the institution by the Outside Interest Committee, to be signed by the Provost and by those individual Investigators who will be implementing the institutional COI management plan provisions. Forms for individual Investigators to document that they do not have an individual conflict of interest would be attached to the institutional COI management plan, as well.

XI. Ongoing Review and Monitoring

A. Amending Management Plans

Outside the annual disclosure process, Investigators must disclose within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest to the university. In addition if the OVPR designee or OIC is notified, either by the investigator or from another source—IRB, research administrative office, etc—that there has been a change in the Investigator’s significant financial interest, in the Investigator’s sponsored research, or in the relationship between

financial interest and sponsored research, then it may be necessary to amend the management plan.

For example, a NIH grant has been awarded that was not previously described in the management plan, and this research is related to the Investigator's financial interest, such that NIH notification is now required. Amended management plans will be drafted by a member of the OVPR, forwarded to the Investigator for comments, and brought to the OVPR designee or OIC for review and approval.

Minor changes that do not materially change the provisions in the management plan (e.g., anticipated research was not funded) can be reviewed administratively by the OVPR and noted in subsequent monitoring reports.

B. Monitoring of Management Plans

Monitoring of the management plan will be scheduled to document compliance with the most recent management plan, to determine whether the relationship between significant financial interests and sponsored research has changed or is expected to change, and to update the management plan based on new information from the Investigator and/or new standards established by the university.

Monitoring will be conducted by a member of the OVPR, in conjunction with the Outside Interest Committee (OIC), as needed. Monitoring of previously drafted management plans will be performed at least once per year for PHS-funded research or research involving human participants. All other management plans will be monitored at least every three years. The OVPR designee or OIC may determine that a management plan requires more frequent monitoring (e.g., involves human subject research). More frequent monitoring may also be initiated if noncompliance is found.

Monitoring will include review of the Investigator's FCOI file. The Investigator will be notified in writing that his/her file has been selected for monitoring and given the reason for such selection (e.g., routine monitoring). Additional information will be requested of the Investigator via interview, written response or site visit.

A monitoring report will be generated by the OVPR, brought before the OVPR designee or OIC for review and approval. A monitoring report must be brought to the OIC for a vote if the original management plan was approved via a vote of the OIC.

The exception to the rule that monitoring reports require a vote would be if upon monitoring, it is determined administratively that there is currently no financial conflict of interest. In such cases the monitoring report would be administratively reviewed and approved. However, OIC members can request that any action taken under administrative review be brought before the OIC for a formal vote.

XII. Records

The university is required to keep all records of Investigator disclosures of financial interests and the review of, or response to, such disclosure (whether or not the disclosure resulted in the university's determination of a FCOI), and all actions under the university policy for at least three years from the date of the submission of the final expenditures report for PHS-funded research or, where applicable, other time periods as required by regulation or sponsor contract terms. When no external requirement exists the university will keep all records for a minimum of three years.

XIII. Public Accessibility

The university is required to make its policy and these procedures available via a publicly available website. The OVPR will be responsible for ensuring that the most current version is posted on a public website. The site will also include a dedicated mailing address and email address where individuals can send written requests for information.

If a FCOI has been identified involving a university PHS-funded research project and the university has received a written request to provide information about the FCOI, the OVPR designee will send a written response within five business days of the request that includes the following information:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the Significant Financial Interest is held;
- Nature of the Significant Financial Interest; and
- Approximate dollar value of the Significant Financial Interest (dollar ranges including, \$0-\$4,999; 5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

XIV. External Reporting of FCOI

A. Public Health Service Research

Prior to expending any funds under a PHS-funded research project where a FCOI has been identified, the university must provide NIH with a FCOI report through the electronic Research Administration (eRA) Commons FCOI module or in writing as determined by the agency. The OVPR will be responsible for ensuring that all reporting requirements are met.

The initial report must be submitted within sixty (60) days after the university has determined that an FCOI exists. However, if the university eliminates the FCOI prior to the expenditure of funds, no report is required. An annual report (i.e., at the time of the submission of the annual progress report or at the time of an extension (with or without funds) is also required that addresses the status of the FCOI (i.e., conflict no longer exists), whether the FCOI is still being managed, and whether there have been any changes to the management plan.

All FCOI reports to PHS should include, but are not limited to, the following elements:

- Project number;
- PD/PI or Contact PD/PI if multiple PD/PI model is used;
- Name of Investigator with the FCOI;
- Name of entity with which the Investigator has a FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of financial interest (see description above);
- A description of how the financial interest relates to the PHS-funded research and why the university determined that the financial interest conflicts with such research;
- A description of the key elements of the university's management plan, including:
 - The role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

B. Retrospective Review and Mitigation Reports for PHS-Funded Projects

The university will conduct a "retrospective review" within 120 days of a determination of any noncompliance findings, which include:

- Failure by the Investigator to disclose a Significant Financial Interest (SFI) that is determined by the university to constitute a FCOI;
- Failure by the university to review or manage such a FCOI; or

- Failure by the Investigator to comply with the FCOI management plan.

The retrospective review will normally be conducted by the OVPR in coordination with the Outside Interest Committee and will document at least the following key elements:

- Project number;
- PD/PI or Contact PD/PI if multiple PD/PI model is used;
- Name of Investigator with the FCOI;
- Name of entity with which the Investigator has a FCOI;
- Reason(s) for retrospective review;
- Detailed methodology used for the retrospective review (e.g., composition of the review panel, documents reviewed, etc.);
- Findings of the review, and
- Conclusions of the review.

If bias is found, the OVPR will promptly notify PHS and send a mitigation report that includes the following:

- Key elements described above;
- Description of the impact of the bias on the research project; and
- University's plan to eliminate or mitigate the effect of bias.

The OVPR will then send annual reports to PHS as described above.

C. National Science Foundation (NSF) Research

Prior to expending any funds under a NSF-funded research project the university must ensure that all financial conflicts of interest are managed, reduced or eliminated. If the university decides that it cannot manage, reduce or eliminate the FCOI or if research proceeds without the imposition of conditions or restrictions when a conflict of interest exists, the OVPR will notify NSF electronically via the NSF Fastlane System in accordance with NSF's "Conflicts of Interest Policy."

XV. Training

All Investigators who are involved with a PHS grant or cooperative agreement will receive initial FCOI training prior to engaging in NIH-funded research and at least every four years they remain engaged in PHS-funded research. Investigators must also be trained as soon as possible under the following circumstances:

- When the university Financial Conflict of Interest policies and procedures change in a manner that affects Investigator requirements; or
- When an Investigator is new to the university; or

- When the university finds that an Investigator is noncompliant with the university's policy or applicable management plan.

The OVPR will determine the content and method of such training and communicate the requirements to the applicable Investigators in a timely manner. Such training will always include information on the university's disclosure process and FCOI policy. Current training requirements are posted on the University's FCOI website at:

<http://www.wright.edu/rsp/coi.html>.

WSU Sponsored and Reimbursed Travel Procedures

The purpose of these procedures is to define the process by which sponsored and reimbursed travel related to an investigator's institutional responsibilities is disclosed to the university. As well as, to define how the university will review those disclosures in order to identify any real or potential financial conflicts of interest. These procedures also describe the university's compliance efforts with regard to Public Health Service (PHS) regulation 42 CFR, part 50, subpart F and 45 CFR Part 94.

Responsibilities

The Outside Interest Committee (OIC) will be responsible for approving any revisions to these procedures, for defining the information that will be collected from investigators, and for setting categories of sponsored or reimbursed travel that can be exempt from further review.

Investigator Disclosure

All PHS-funded investigators (hereafter referred to as "investigators") must disclose any sponsored or reimbursed travel that occurred 12 months before the date of their annual disclosure or planned for the 12 months after the date of the disclosure. In addition, investigators must disclose travel that was not disclosed on the annual form no more than 30 days after the last day of their trip. However, travel that is funded through WSU or sponsored or reimbursed by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education does not need to be disclosed. Travel will be disclosed using the COI Disclosure forms.

Initial Review of Disclosures

A member of the OVPR will initially review the disclosures to determine whether each disclosure is either exempt from further review or requires full review. "Exempt from review" means that the university has determined that even if the significant financial interest was related to PHS-funded research it would not constitute a real or perceived financial conflict of interest.

Categories of sponsored and reimbursed travel that would be exempt from further review are as follows:

- Sponsored or reimbursed travel by an investigator who does not conduct human subject research that is valued at less than \$5,000 per trip and the investigator has no other significant financial interests with the same entity; or

- Sponsored or reimbursed travel by an investigator who conducts human subject research that is valued at less than \$2,000 per trip and the investigator has no other significant financial interests with the same entity.

In some circumstances, the initial reviewer may determine that the individual disclosure should receive full review even though it may have met the above criteria for exemption. In those cases, the initial reviewer will document the reason for the referral on the disclosure form.

Full Review

A member of the OVPR will review the referred disclosure and collect the information needed to determine whether the sponsored or reimbursed travel is related to the investigator's PHS-funded research. This may involve interviewing the investigator.

If it is determined that the sponsored or reimbursed travel **is not** related to the investigator's PHS-funded research, that determination will be documented on the disclosure form and the investigator will be notified that the review is closed.

If it is determined that the sponsored or reimbursed travel **is** related to the investigator's PHS-funded research, the disclosure will be referred to the Outside Interest Committee to be reviewed and managed through the committee's normal process.