



POLICY & PROCEDURE DOCUMENT

NUMBER: 2.7504

DIVISION: Research

TITLE: Financial Conflict of Interest in Extramural Contracts & Grants

DATE: January 2013

REVISED: May 9, 2016; August 15, 2018, February 14, 2022, September 28, 2023

AUTHORIZED BY: Robert Fischer, Provost and Vice President for Academic Affairs

I. Purpose and Scope

A. Background

1. Western Kentucky University (WKU) has published high standards for Faculty conduct, including the conduct of research, in the WKU Faculty Handbook and in its Policies and Procedures. All WKU Investigators are expected to carry out research consistent with these standards.
2. Even when these high standards have been met, conflicts of interest or perceptions of conflicts may still occur when an Investigator's private interests converge with their research interests, such that an independent observer might reasonably question whether the Investigator's professional actions or decisions are improperly influenced by considerations of personal financial benefit or personal gain. Such conflicts are common in universities and do not impugn the character or actions of any individual.
3. WKU policy requires that any Investigator (i.e. any WKU employee responsible for the design, conduct, or reporting of a sponsored project at WKU) is required to disclose significant personal and/or financial interests related to their institutional responsibilities pursuant to circumstances specified by this policy.
4. When WKU reasonably determines that the significant personal and/or financial interest could directly and significantly affect the design, conduct, or reporting of the research, WKU will take steps either to manage or to eliminate any such conflicts of interest.

B. Purpose

This policy is intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded or not

funded under externally sponsored grants, contracts, and cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

C. Scope

This policy shall apply to all research and externally sponsored projects carried out at all units of WKU. Updated information regarding specific institutional and sponsoring agency requirements is located at <https://www.wku.edu/sponsoredprograms>.

II. Policy

A. General

This policy implements federal requirements pertaining to “Promoting Objectivity in Research” and “Responsible Prospective Contractors” promulgated by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 and 45 CFR Part 94. This policy also implements federal requirements contained in the National Science Foundation’s “Investigator Financial Disclosure Policy.” Both agencies require WKU to maintain an appropriate written policy on conflict of interest disclosure as a condition for receiving federal grants. These federal requirements, as implemented in this policy, are applicable to all proposals for extramural awards submitted to federal agencies.

B. Responsibilities and Administration

1. The Associate Provost for Research and Graduate Education, in consultation with the Provost and Vice President for Academic Affairs, is responsible for implementation of this policy.
2. Records regarding Disclosures, Reviewing Official(s) determinations, Financial Conflict of Interest Committee recommendations, and WKU actions regarding management of a conflict of interest must be retained for three years beyond the termination or completion of an award, or until resolution of any action by the sponsor involving the records, whichever is longer.
3. Implementation of this Policy shall include compliance with applicable sponsor regulations governing institutional responsibilities, certification of compliance, reporting requirements, and other duties required under the specific sponsor's regulations.

C. Definitions

The definitions of terms shall be those as defined by 42 CFR Part 50.

Disclosure of significant financial interests means an Investigator’s disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, 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, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

- A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner, and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - 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 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); 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;
 - 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 when the Investigator (or the Investigator's spouse, domestic partner, or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 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 income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 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.

III. Procedure

A. FCOI Training Requirements

1. Investigators must complete FCOI training through the WKU Office of Research Integrity if required by the sponsor. 42 CFR 50.604(b) indicates that each institution shall inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - a. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - b. An Investigator is new to an Institution; or
 - c. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

B. Disclosure of Financial Interests

1. All individuals submitting applications for external funding must complete a Financial Conflict of Interest Disclosure Form annually, whether or not the individual has financial interest to report. Individuals are also required to complete the Financial Conflict of Interest Disclosure Form within thirty (30) days of acquiring a new significant financial interest. The Disclosure Form shall include the financial interests of the Investigator and those of their spouse, domestic partner, and dependent children.
2. Disclosures must be current throughout the duration of the project. An updated Disclosure Form must be submitted at least annually during the period of the award. If the disclosure has lapsed, project funding may be withheld until an updated Disclosure Form has been reviewed and approved.
3. For all proposals submitted to external sponsors, all senior/key personnel must indicate during the routing process whether a financial conflict of interest may exist.

C. Disclosure Form

A Financial Conflict of Interest Disclosure Form is available at the Office of Research Integrity website.

An Investigator must:

- (a) Indicate whether the Investigator (including their spouse, domestic partner, or dependent children) has any significant financial interests related to their institutional responsibilities;
- (b) Provide the name of each entity in which the Investigator has a significant financial interest and the type of the financial interest (income, equity, management position, or intellectual property);
- (c) Indicate whether the entity in which the Investigator has a significant financial interest is a proposed subcontractor, consortium member, supplier of goods, lessor, or otherwise involved with the sponsored project(s);
- (d) Indicate whether the entity in which the Investigator has a significant financial interest might manufacture or commercialize any drug, vaccine, device, procedure or any other product involved in or that will predictably result from the sponsored project(s);
- (e) Indicate whether or not he or she believes the project(s) could directly and significantly affect the related financial interest(s) he or she is reporting; and
- (f) Accept that the disclosure will be open to public inspection. The principal purpose for requesting the information on this form is to comply with WKU policy and federal regulations regarding disclosure of any financial interests that would reasonably appear to be affected by the conduct of a sponsored project. Provision of the information is mandatory if you want to submit a proposal for support of a project covered by the terms of this policy. The information may be released or transmitted to the sponsor, including federal agency representatives, and, according to state law, may also be released to the public upon request.

D. Subrecipient Agreements

To ensure that WKU fulfills its obligations under 42 CF Part 50 and 45 CFR Part 94, subrecipients who participate in PHS-funded research shall agree in writing to either: 1) comply with the applicable requirements of the FCOI policy of the awardee Institution; or 2) certify that the subrecipient has a financial conflict of interest policy that complies with 42 CF Part 50 and 45 CFR Part 94 and will timely report any related conflicts of interest to the WKU Office of Research Integrity. The subrecipient shall meet timelines set by the awardee institution allowing appropriate reporting by the awardee institution according to regulation and sponsor requirements.

E. Financial Conflict of Interest Committee (FCOIC)

1. The FCOIC shall be appointed by the Associate Provost for Research and Graduate Education in consultation with the Provost and Vice President for Academic Affairs.
2. The Compliance Manager, Compliance Associate, and an Office of Sponsored Programs staff shall serve *ex officio* on this committee.
3. The FCOIC shall be composed of a minimum of five (5) members.
4. The FCOIC shall be advisory to the Associate Provost for Research and Graduate

Education.

F. Review of Disclosures

1. Financial Conflict of Interest Disclosure Forms shall be reviewed administratively by the Office of Research Integrity. Any conflicts disclosed will be reviewed by the FCOIC to determine whether any reported significant financial interest, could be affected by the funded research; or is an entity whose financial interest could be affected by the sponsored research/project.
2. A financial conflict of interest exists when the FCOIC reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the sponsored research/project.
3. A direct impact occurs when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator (including their spouse, domestic partner, or dependent children) has a financial interest, or when the entity is a proposed subcontractor or participant in the project. A significant impact on the financial interest is one that will materially affect the value of the entity, its earnings, or the sales of its products, or the entity is a proposed subcontractor or participant in the project.
4. Based on information provided in the Disclosure, the FCOIC may determine that there is no reasonable basis on which to conclude that a project could affect the financial interest and/or that the financial interest is not likely to directly and significantly affect the design, conduct, or reporting of the project. In this case, a record should be made of the Reviewing Official(s) or Committee's action and the project can proceed without further review.
5. In the event that the FCOIC or the Office of Research Integrity reasonably concludes that a project could have an impact on the financial interest and that the financial interest could directly and significantly affect the design, conduct or reporting of the project, the Disclosure and appropriate documentation shall be forwarded to the Associate Provost for Research and Graduate Education. The Associate Provost for Research and Graduate Education, working with the FCOIC and ORI, will make a final decision about the appropriate actions that are necessary to manage the conflict of interest. The same review process takes place when an Investigator files an updated form reporting a new significant financial interest.

G. Management or Elimination of Conflicts of Interest

1. When it is reasonably determined that an Investigator has financial conflict of interests that could directly and significantly affect the design, conduct, or reporting of the research/sponsored project, the FCOIC will recommend implementing a plan and procedures to manage the conflict of interest in order to minimize the effect of the related Significant Financial Interest(s) on the design, conduct, or reporting of the sponsored project(s). Investigators also may be asked to make recommendations best managing the conflict of interest.
2. Examples of conditions or restrictions that may be imposed to manage or eliminate conflicts of interest include:
 - (a) Public disclosure of financial conflicts of interest(s) when presenting or

publishing research;

(b) For projects involving human subject research, disclosure of financial conflicts of interest directly to subjects;

(c) Monitoring of the project by independent reviewers capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from financial conflicts of interest;

(d) Modification of the research or project plan;

(e) Disqualification of Investigator(s) from participation in all or a portion of the project;

(f) Reduction or elimination of the financial conflict of interest (e.g., sale of an equity interest);

(g) Severance of relationships that creates the financial conflict of interest.

3. Alternatively, the Associate Provost for Research and Graduate Education may determine that the project not be undertaken by WKU if it is determined that the conflicts cannot be managed satisfactorily.

4. The review of the Disclosure(s) and adoption of conditions or restrictions to manage or eliminate the conflict of interest must be completed prior to expending funds made available under the sponsored award. When required, a report of the existence of a conflict of interest and assurance that it has been managed, reduced, or eliminated, must be submitted to the sponsoring agency.

H. Institutional Reporting Requirements

1. The Associate Provost for Research and Graduate Education or designee shall be responsible for institutional compliance with all sponsoring agency reporting requirements, including all reporting elements required by 42 CFR 50.604(h) and 42 CFR 50.605(b).

2. Any FCOI related to PHS-funded research (that could directly or significantly affect the design, conduct, or reporting of the research) shall be identified, managed, and reported to the PHS-Awarding Component prior to the expenditure of any project funds.

3. Any related FCOIs that arise after the project begins shall be managed and reported within sixty (60) days of disclosure.

4. PHS reports shall be updated on an annual basis for the duration of the research project. Annual reporting must be completed at the same time that the annual progress report is submitted. It may also be necessary to submit a PHS report following a retrospective review in order to update a previously submitted report.

5. The PHS-Awarding Component shall be notified promptly if bias is found with the design, conduct or reporting of PHS-funded research. A complete Mitigation Report will be submitted that includes all reporting elements in accordance with 42 CFR 50.605(a)(3)(iii).

6. The PHS-Awarding Component shall be notified promptly if an Investigator fails to comply with the institution's FCOI policy, or if a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research (42 CFR 50.606(a)).

I. Enforcement Mechanisms and Remedies and Noncompliance

1. Failure to file a complete Financial Conflict of Interest Disclosure Form or Update Form⁷, or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be grounds for disciplinary action pursuant to the relevant WKU policies related to faculty conduct or other applicable employee disciplinary policies.
2. In the event that the Associate Provost for Research and Graduate Education and the FCOIC determine that a substantial failure to comply has occurred, this shall be conveyed to the Provost and Vice President for Academic Affairs who shall determine disciplinary action in accord with WKU policies.
3. Federal regulations may require reports to the federal sponsor of any information that may show a violation of WKU policy. Such reports shall be made by ORI in consultation with the Associate Provost for Research and Graduate Education and the Provost and Vice President for Academic Affairs.
4. Retrospective reviews shall be completed and documented within 120 days of the determination of noncompliance whenever an FCOI is not identified or managed in a timely manner. Reviews shall be documented consistent with 42 CFR 50.605(a)(3)(ii)(A).
5. In any case in which the Department of Health and Human Services determines that a PHS- funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required by the regulation, the Investigator involved shall be required to disclose the FCOI in each public presentation of the results of the research, and to request an addendum to previously published presentations (42 CFR 50.606(c)).
6. Sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of significant financial interests related to federally sponsored projects.

J. Public Accessibility Requirements

1. WKU's Financial Conflict of Interest in Extramural Contracts & Grants policy is publicly available on the Institutional Policies website.
2. Identified FCOIs held by senior/key personnel (as defined by 42 CFR Part 50) will be made publicly accessible prior to the expenditure of funds. The information provided will include the minimum elements as provided by the regulation (42 CFR 50.605(a)(5)(i)-(iv), will be made available within five calendar days of a written request, will be updated at least annually, will be updated within 60 days of a newly identified FCOI, and will remain available for three years from the date the information was most recently updated.

IV. Related Policies

Policy 0.000V Policy on Policies

V. Reason for Revision

May 9, 2016

Revised to reflect re-organization of the Office of Research and Creative Activity

August 15, 2018

Revised to ensure that WKU is in full compliance with local, state, and federal requirements (including 42 CF Part 50 and 45 CFR Part 94).

February 2022

Revised to reflect the changes in leadership and position title, clarity in handling FCOIC disclosures, as well as the new procedure for accessing and submitting the FCOI Disclosure Form using IRBNet.org.

October 2023

Revised to change requirement regarding when FCOI Disclosure Form must be submitted and to remove the IRBNET.org procedure language.

VI. Appendix: Disclosure of Financial Conflict of Interest Form

Western Kentucky University recognizes that relationships with external entities can be useful in many ways. WKU encourages these relationships as they enhance personal competency and benefit the community and the institution. However, these relationships can create the potential for conflict of interest where an individual's financial or personal considerations may affect or appear to affect their WKU activities related to externally sponsored programs. The identification of real or apparent conflict of interest does not necessarily imply any improper activities or motives on the part of the individual.

What is a Financial Conflict of Interest?

A financial conflict of interest occurs when there is a divergence between an individual's private interests and their professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain. Potential and actual financial conflicts of interest depend on the situation and both must be managed accordingly. Financial interest means anything of monetary value, whether or not the value is readily ascertainable. *See full definition of significant financial interest Policy 2.7503.*

What is the purpose of this form?

This form seeks to identify financial conflicts of interest that must be managed:

- to help assure the ethical, non-biased conduct of research and sponsored programs,
- to address federal regulations governing externally-sponsored programs, and
- to help protect both the institution and investigators in limiting their liabilities in the conduct of university-affiliated activities.

Who should complete this form?

Any Principal Investigator (PI) completing a funding proposal and any senior/key personnel identified. Senior/key personnel is defined as any individual, regardless of title, responsible for the design, conduct, or reporting of externally funded research.

When do I complete this form?

Annually, and if circumstances change (e.g. if a new conflict of interest is identified), a PI or senior/key personnel must immediately submit a new form or updated disclosure within 30 days of any subsequently identified FCOI.

How do I complete the form?

Instructions for Financial Conflict of Interest form completion can be found at <https://www.wku.edu/compliance/>.

Where can I learn more about FCOI regulations?

Visit <https://grants.nih.gov/grants/policy/coi/>.