

<p>Category:</p> <p>Administrative</p> <p>Policy applicable for: Faculty/Staff</p>	<p><i>Policy Title:</i> Conflict of Interest on Externally Funded Projects</p> <p>Effective Date: 12/1/2013</p> <p>Prior Effective Dates: 08/21/2012; 04/14/2009 (Previous title: Conflict of Interest on Federally Sponsored Projects)</p> <p>Enabling Acts: University Rule 3361:10-17-08, 10-17-09 42 CFR 50 Subpart F 45 CFR Part 94 NSF 07-140 Chapter IV</p>	<p><i>Policy Number:</i> 1.3.2</p> <p>Policy Owner: VP for Research</p> <p>Responsible Office(s): Sponsored Research Services General Counsel Office of Research</p>
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I. Purpose

The purpose of this policy is to assure that the objectivity and integrity of the researcher, the University of Cincinnati (UC), and academic research, training, or other activities are not compromised or perceived to be compromised by matters of financial benefit or personal gain.

The policy provides the university's approach to identifying individual financial relationships, evaluating, and determining potential financial conflicts of interest related to research activities as well as developing strategies to manage conflicts. This policy assists faculty, staff, and students in meeting their obligations to conduct research responsibly, ethically, and objectively and to comply with applicable federal, state, and local regulations and university rules and policies.

II. Scope

This policy applies to all university faculty, staff, and students (including post-doctoral fellows and scholars) regardless of title or position, involved in designing, conducting, or reporting of research as part of their university duties, which includes, but may not be limited to, a principal investigator, co-investigator, project director, and key personnel.

III. Definitions

For purposes of this policy, the following definitions shall apply:

Conflict of Commitment shall mean an external activity that interferes with academic, clinical, scholarly, or administrative responsibilities at UC. UC employees (UCE) may engage in outside activities which contribute to professional development by enhancing knowledge, skills, and expertise. Such activities may include consulting, authorship, editorial services, involvement with professional societies, or participation on educational, advisory, or scientific committees and review panels. Such activity, however, should not interfere with a UCE's Institutional Responsibilities. Therefore, outside activities must be reviewed and approved by the appropriate UC Officials(s) (see University Rules 3361: 30-21-01, 02, 03 and 10-17-08 in *Related Links*).

Conflict of Interest shall mean a set of circumstances that creates a risk that professional

judgment or actions regarding a primary interest will be unduly influenced by a secondary interest. Primary interests refer to the principal goals of the profession or activity, such as the health of patients and the integrity of research. Secondary interests include not only financial gain but also such motives as the desire for professional advancement and the wish to do favors for family and friends. A conflict of interest exists if the circumstances are reasonably believed (on the basis of past experience and objective evidence) to create a risk that decisions may be unduly influenced by secondary interests.

Conflict Management Plan (CMP) shall refer to a document that entails information regarding an outside activity as it relates to research being conducted at UC coupled with specific method(s) to manage the conflict which will be reviewed at least annually by UC Officials and/or the Conflict of Interest Committee.

Fiduciary Relationship shall mean a relationship that results in a legal or ethical obligation to act in the best interest of an organization (such as service as a board member, officer, executive, advisor, or manager), regardless of whether compensation is received for services.

Financial Conflict of Interest shall mean a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of Public Health Service (PHS) research, National Science Foundation (NSF) research, and non-government funded research.

Immediate Family shall mean a spouse, dependent child, domestic partner, children, parents, grandparents, and siblings.

Institutional Responsibilities shall mean the UCEs responsibilities associated with or resulting from his or her university appointment or position. Institutional responsibilities may include but are not limited to: research; education/teaching; professional activities; administration; and services to the university and to internal and external professional organizations.

Investigator is defined as the Principal Investigator/Project Director and any other person who is responsible for the design, conduct, or reporting of research, or proposed for such funding, including subgrantees, contractors, or collaborators. For purposes of this policy, UCE includes the definition of Investigator.

Manage shall mean taking action(s) to address a COI to ensure that the design, conduct, and reporting of research will be free from bias.

Outside Activity Report (OAR) shall refer to the electronic disclosure form that is required to be submitted at least annually by UCEs and any non-university personnel who act as an investigator at the university. UCEs should disclose all personal financial interests and those of their family, regardless of value, that appear to be related to the employee's Institutional Responsibilities.

Research shall mean a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. This includes basic, behavioral, and social sciences research and encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development research (e.g., diagnostic test or drug).

Significant Financial Interest (SFI) includes any of the following interests of a UCE or his/her Immediate Family that **reasonably appear to be related to a UCEs Institutional Responsibilities:**

- a) With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from a single 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 options, 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 SFI exists if the value of any remuneration received from a single entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the UCE (or the UCE's immediate family) holds any equity interest (e.g., stock, stock options, or other ownership interest); or
- c) Intellectual property rights and interests (e.g., patents, copyrights), when there is a right to receive income related to such rights and interests.
- d) UCEs 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. UCEs shall disclose the dates of travel, destination, entity that paid for the travel, purpose of the trip, and travel paid for the individual's spouse and/or dependent child(ren) by the entity (if applicable) (42 CFR 50.603).

Significant Financial Interest (SFI) shall not include:

- a) Salary, royalties, or other remuneration paid by the University to the UCE if the UCE is currently employed or otherwise appointed by the University, including intellectual property rights assigned UC and agreements to share in royalties related to such rights;
- b) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the UCE does not directly control the investment decisions made in these vehicles;
- c) 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;
- d) 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; or
- e) Salary earned through employment with University of Cincinnati Physicians, Inc.

Technology Transfer shall mean the commercialization of ideas, concepts, and inventions through publication, patenting, and licensing, and the formation of business entities.

UC shall mean the University of Cincinnati in its entirety, including, but not limited to, colleges, departments, and administrative offices.

UCE shall mean all University of Cincinnati employees (faculty, staff, and trainees) which include all UC principal investigators, co-principal investigators, and any other individual at UC who is responsible for the design, conduct, or reporting of research performed at UC. UCEs also include the individual's Immediate Family members.

UC Official shall mean the president, vice presidents, deans, department chairs, division directors, members of the Entrepreneurial Affairs and Technology Commercialization Office and UC's Conflict of Interest Office, and any other individual in a position to make or significantly influence decisions on behalf of UC involving oversight of research, execution of grants or contracts, or licensing of UC intellectual property to external parties.

IV. Policy and Procedure

Concerns about conflicts of interest arise when UCEs have private interests, such as outside professional or financial relationships, that may unduly influence or appear to inappropriately influence professional judgments involving their primary interests and responsibilities to UC. While these instances do not necessarily imply wrongdoing, the perception that such incentives might adversely affect patients, research objectivity, the protection of human subjects, or UC's mission is sufficient to require that both potential and actual conflicts of interest be disclosed and appropriately managed. Therefore, UCEs shall disclose outside activity so that designated UC Officials may determine if the relationship reasonably appears to be related to the UCE's Institutional Responsibilities. A disclosure that is considered a potential conflict of interest must be disclosed fully and accurately in all formal communications that may be impacted by the financial interest, including abstracts, publications, presentations, press releases, and applications or proposals for research funding.

Disclosure

Employees who are considered Investigators at UC and any non-UC personnel who act as an Investigator at UC are required to disclose all outside activities and financial interests on their OAR form as provided in University Rule 30-21-01. UCEs are required to complete the OAR annually and within thirty (30) days of acquiring a new significant financial interest (SFI). New employees are required to complete the OAR within the first two (2) weeks of employment. Disclosures must also be current any time a grant application or research protocol is submitted and must remain current throughout the duration of the research project. Disclosures must include any SFI of the UCE and his/her Immediate Family Members that could reasonably appear to be related to the UCE's Institutional Responsibilities. A UCE who has not submitted an OAR or whose OAR has expired will not be allowed to conduct research or submit new grant applications until a current OAR has been submitted.

Disclosures containing potential conflicts of interest shall be forwarded to the Director of Research Affairs in the Conflict of Interest Office, Conflict of Interest Committee, and the Vice President for Research for review and management, if applicable. Please refer to the OAR Guidance document for further information regarding conflict management procedures.

Conflict of Interest Committee (COIC)

The COIC is a standing faculty committee, designated with the responsibility to provide an independent peer-reviewed assessment of personal financial interests reported by UCEs. See University Rule 3361:10-17-08 for committee appointment and composition. The COIC shall identify and manage conflicts of interest of UCEs as they relate to research. Any conflicts of commitment identified will be referred to the appropriate UC Official.

COIC Determinations

The COIC shall consider the following: the nature of the research, the magnitude of the financial interest, the degree to which the interest is related to the research, the extent to which the research performance, outcome, or both could affect the value of the interest, the potential to introduce bias by study design, performance, or interpretation, and/or the degree of risk to the human subjects involved. The COIC shall consider whether the SFI could directly and significantly impact the research. A **direct** impact is one where research results could be directly relevant to development, manufacturing, or improving products or services of an entity or technology in which the UCE has a SFI. A **significant** impact is one that could materially affect the value of the technology or the entity, its earnings, or sales (see 42 CFR 50.604(f)). Common SFIs that can lead to conflicts of interest related to research include, but are not limited to:

- a) Equity or proprietary interests that could increase or decrease in value based on the outcome of the research;
- b) Financial or fiduciary relationships with private entities that could benefit based on the outcome of research;
- c) Gifts, endowments, or contributions from private entities that could benefit based on the outcome of research.

If the COIC determines that a conflict of interest exists, the COIC shall make recommendations to manage, reduce, or eliminate the conflict. The UCE will be asked to complete a Conflict Management Plan (CMP) which requires specific details about the financial relationship, the research related to the relationship, UC responsibilities, and UC research. The CMP will also include the recommendations for management provided by the COIC as well as UCE certifications and agreement.

Management of Conflicts of Interest

Methods for managing conflicts of interest may vary based on the specific facts of each situation. Please see UC's Conflict of Interest Office's Guidelines and Procedures document (in *Related Links*).

PHS-Funded Research

Any conflicts of interest related to PHS-funded research shall be identified, managed, and reported to the PHS-Awarding Component prior to the expenditure of any funds under the research project. Any related conflicts of interest that arise after the project begins shall be managed and reported within sixty (60) days of disclosure. PHS reports shall be updated on an annual basis for the duration of the research project (42 CFR 50.605). Annual reporting must be completed at the same time as when the UCE is required to submit to the NIH the annual progress report, multi-year progress report, if applicable, or at time of extension (with or without funding).

DHHS Requirements

In the event the Department of Health and Human Services (HHS) 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 a UCE with a financial conflict of interest that was not appropriately managed or reported, the UCE shall be required to publicly disclose the conflict of interest and to request an addendum to previously published presentations (42 CFR 50.606(c)).

Reimbursed or Sponsored Travel

UCEs who are planning to participate in research must disclose their reimbursed or sponsored travel related to their institutional responsibilities over the previous 12-month period (initial disclosure) no later than at time of the application for research. UCEs must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Public Accessibility

UC shall provide to any requestor written information about conflicts of interest, which were determined to be a SFI related to PHS-funded research on or after August 24, 2012, in accordance with 42 CFR Part 50 and 45 CFR Part 90 and this procedure. UCEs with SFI related to PHS-funded research shall remain available upon written request for three years from the date that the disclosure information was most recently updated (42 CFR 50.605(a)(5)(iv)). For additional information, please see Guidelines and Procedures document (in *Related Links*).

PHS-Funded Research and Subrecipient Agreements

To ensure that UC fulfills its obligations under 42 CF 50.605, subrecipients who participate in PHS-funded research shall agree in writing to either: 1) comply with the applicable requirements of this policy; or 2) certify that the subrecipient has a conflict of interest policy that complies with 42 CFR Part 50 Subpart F and timely report any related conflicts of interest to the UC Conflict of Interest Office. Guidelines and Procedures document (in *Related Links*).

Noncompliance

When the results of monitoring (or other instances) identify a potential failure to comply with UC's policies and processes governing conflicts of interest in research, the director of UC's Conflict of Interest Office and the COIC will conduct an assessment of the situation and make a determination as to whether the individual failed to comply and the extent of the non-compliance. The director and chair of the COIC may involve/discuss the potential compliance failure with the UCE and/or others to make a determination which may include internal audit and other mechanisms of investigational inquiry. Results of internal audit could lead to issues of noncompliance.

A UCE is noncompliant when, for example, s/he **fails** to:

1. Report SFIs accurately, fully, and in a timely manner;
2. Complete mandatory training;
3. Provide additional information as requested by the COIC;
4. Comply fully and promptly with management plans or decisions of the COIC, subject to the reconsideration process set forth herein; and
5. Update disclosures as required herein.

If the COIC has reasonable cause to believe that the UCE has failed to comply with this policy or a management plan, it shall inform the UCE of the basis for such belief and afford the UCE an opportunity to explain the alleged compliance failure. For further procedural information, please see the Guidelines and Procedures document (in *Related Links*).

Retrospective Reviews

In the event that a SFI is identified that was not timely disclosed or reviewed, the COIC shall determine if the SFI constitutes a conflict of interest and whether it is related to PHS-funded research within sixty (60) days of discovery. If a conflict of interest exists, a management plan will be implemented to manage the conflict of interest going forward and the PHS-awarding

component shall be notified. In addition, a *retrospective review* will be conducted anytime a conflict of interest related to PHS-funded research is not identified and managed in a timely manner due to:

- a) Failure of a UCE to timely disclose a SFI that the COIC determines to be a conflict of interest;
- b) Failure of the UC Conflict of Interest Office and/or COIC to timely identify and manage a conflict of interest; or
- c) Failure of a UCE to comply with a management plan (see 42 CFR 50.605).

UC shall, within 120 days of its determination of noncompliance, complete the review of the UCE's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The Office of Internal Audit may be requested to provide assistance, depending on the nature of the review. The retrospective review will be documented; such documentation shall include, but not necessarily be limited to, all of the following key elements: project number; project title; PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the UCE with the financial conflict of interest; name of the entity with which the UCE has a financial conflict of interest; reason(s) for the retrospective review; detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); findings of the review; and conclusions of the review. For further procedural information, please see the Guidelines and Procedures document (in *Related Links*).

Based on the results of the retrospective review, if appropriate, UC shall update the previously submitted financial conflict of interest report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, UC will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component (42 CFR 50.605(a)(3)(iii)). Thereafter, UC will submit financial conflict of interest reports annually, as required by the regulations.

Noncompliance Reporting

Noncompliance with a plan to manage or eliminate a conflict of interest related to federally-funded research that appears to have biased the design, conduct, or reporting of such research, shall promptly be reported to the appropriate PHS Awarding Component (42 CFR 50.606(a)).

Dispute Resolution: Requests for Reconsideration

Unresolved disagreements concerning the application of this policy or with the decision of the Vice President for Research may appeal by delivering a written notice of appeal to the UC Conflict of Interest Office within fourteen (14) days of the date of the decision sent to the researcher. Please see board rule 10-17-08 for additional information.

V. Miscellaneous

- a) Monitoring for Compliance: UC will provide regular monitoring of OAR disclosures and management plans to determine compliance with this policy, and applicable federal regulations, or sponsoring agency requirements.
- b) Confidentiality: The information received to comply with this policy shall be handled confidentially, to the extent possible and/or as described in this policy, unless public disclosure is part of the management plan or such disclosure is required by UC, federal regulations, or sponsoring agencies.
- c) Record Retention: Records of disclosures related to PHS-funded research projects shall

be retained for a minimum of three (3) years from the date of submission of the final expenditures report. Records will include the UCE's disclosures of financial interests and UC's review of, and response to, such disclosures. Records of other disclosures shall be retained for a minimum of five (5) years. In the event of litigation or audit prior to record destruction, applicable records shall be retained until litigation or audit findings involving the records have been resolved and final action taken (42 CFR 50.604(i)).

- d) Policy Disclosure: This policy will be made publicly available on the UC website in accordance with 42 CFR 50.604(a).

Related links:

[Office of Research](#)
[University \(Board\) Rules](#)

Phone Contacts:

Conflict of Interest Office	556-5501
Office of General Counsel	556-3483
Office of VP for Research	558-0026
Sponsored Research Services	558-5540