

<p>Category:</p> <p>Administrative</p> <p>Policy applicable for: Faculty/Staff</p>	<p><i>Policy Title:</i></p> <p>Individual Conflicts of Interest on Externally Funded Projects</p> <p>Effective Date: 08/01/2024</p> <p>Prior Effective Dates: 12/01/2013; 08/21/2012; 04/14/2009 (Previous title: Conflict of Interest on Externally Funded Projects)</p> <p>Enabling Acts: University Rule 3361:10-17-08, 10-17-09 42 CFR 50 Subpart F 45 CFR Part 94 NSF Chapter IX NASA GIC 23-07 (Section 3.3) FAL 2022-02 CFR 200.112, 2 CFR 200.318(c)(2)</p>	<p><i>Policy Number:</i></p> <p>1.3.2</p> <p>Policy Owner: VP for Research</p> <p>Responsible Office(s): Research Security and Ethics Sponsored Research Services Office of Research</p>
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I. Purpose

The purpose of the Individual Conflicts of Interest on Externally Funded Projects Policy (“Policy”) is to assure that the objectivity and integrity of the Investigator, the University of Cincinnati (the “University” or “UC”), and Research, training, or other activities are not compromised or perceived to be compromised by matters of financial benefit or personal gain.

This Policy outlines UC’s approach to identifying and evaluating individual financial relationships, determining potential financial conflicts of interest related to research activities, and developing strategies to manage those 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 as well as 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, who are involved in designing, conducting, or reporting of Research as part of their University duties, which may include, but not be limited to, Investigators, project directors, and/or key personnel.

III. Definitions

For purposes of this Policy, the following definitions apply:

Conflict of Commitment (“COC”) arises when an Investigator accepts or incurs external obligations (foreign or domestic), either paid or unpaid, that conflict or appear to conflict with their primary

obligation and commitment to the University. A Conflict of Commitment exists when Outside Activities:

1. Interfere with an Investigator's ability to fulfill University expectations, obligations, and/or responsibilities; and/or
2. Competes with services that the University provides to include its education, research, or service missions; and/or
3. Involve obligations to improperly share information with an entity outside the University.

Conflict of Interest Officer ("COI Officer") is responsible for overseeing the implementation and enforcement of this Policy. The COI Officer is responsible for developing, promulgating, and updating procedures and guidelines for the implementation of this Policy and for providing administrative support to the Conflict of Interest Committee. The COI Officer is also responsible for ensuring compliance with all applicable U.S. federal regulations and requirements concerning conflicts of interest (see, e.g., 42 C.F.R. §§ 50.604(d) and 50.605(A)(1) – (3)), including but not limited to: identifying and reviewing Significant Financial Interests to determine if the SFI is related to the research, referral of SFIs to the Conflict of Interest Committee, conflict of interest training, FCOI management, FCOI reporting to sponsoring agencies, monitoring for compliance with Conflict Management Plans, and maintenance of all records relating to disclosures and FCOI management. The COI Officer reports all matters of this Policy to the Vice President of Research per University Board Rule 10-17-08.

Conflict of Interest Committee ("COIC") is a standing University-wide faculty committee that works in partnership with the COI Officer in implementing and enforcing this Policy. COIC members will be appointed by the President and Faculty Senate in accordance with Board Rule 10-17-08 for committee appointment and composition. COIC responsibilities and processes include:

1. Review of all Significant Financial Interest disclosures that may be related to the Investigator's research referred by the COI Officer;
2. The Vice President for Research or the Dean of any college may refer potential conflicts of interest to the committee for review and recommendation;
3. FCOI determinations (as outlined below);
4. Development and implementation of Conflict Management Plans (as outlined below);
5. Review of noncompliance issues brought forward by the COI Officer.

Conflict Management Plan ("CMP") refers to the action(s) taken to address an FCOI, which may include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of Research will be objective and free from bias.

Entity means any domestic or foreign, public or private, for-profit or not for-profit, business, organization, or association; including but not limited to, a sole proprietorship, partnership, corporation, limited liability company (excluding U.S. federal, state, and local government agencies).

Equity Interest is any ownership interest in an Entity, including but not limited to stock or stock option(s) and/or partnership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest ("FCOI") exists when the University reasonably determines that an Investigator's Significant Financial Interest is related to Research that could directly and significantly affect the design, conduct, or reporting of the Research, or present the appearance thereof.

Financial Interest refers to anything of monetary value, whether or not the value is readily ascertainable.

Foreign Talent Recruitment Program (“FTRP”) is any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including Research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an Entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to an individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue.¹

Immediate Family refers to an Investigator’s spouse and/or dependent children.

Institutional Responsibilities refer to an Investigator’s professional duties and responsibilities on behalf of the University. Institutional Responsibilities may include but are not limited to Research; creative and/or scholarly inquiry; education/teaching; professional activities; administration; services to the University; and services to internal and external professional organizations such as grant review panels, data safety monitoring boards, and review boards, etc. These activities are generally expected of an Investigator as part of their professional portfolio and/or service, whether compensated or uncompensated, and are often reflected in an annual performance review, including reappointment, promotion, and tenure criteria.

Investigator is any individual, regardless of their title or position, whether faculty, staff, or student, who has the ability to make independent decisions related to the design, conduct, or reporting of University research. This does not include individuals who perform only incidental or isolated tasks related to a University research project. The term includes individuals who are principal investigators or co-investigators of Research.

Malign Foreign Talent Recruitment Program is defined as:

1. Any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including Research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an Entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to the targeted individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue, in exchange for the individual² –
 - a. Engaging in the unauthorized transfer of intellectual property, materials, data products, or other nonpublic information owned by a United States Entity, including University, or developed with a federal research and development award to the government of a foreign country or an Entity based in, funded by, or affiliated with a foreign country regardless of whether that government or Entity provided support for the development of the intellectual property, materials or data products;

¹ H.R. 4346 – 117th Congress (2021-2022): Chips and Science Act, TITLE VI – MISCELLANEOUS SCIENCE AND TECHNOLOGY PROVISIONS Subtitle D (Sections 10631).

² H.R. 4346 – 117th Congress (2021-2022): Chips and Science Act, TITLE VI – MISCELLANEOUS SCIENCE AND TECHNOLOGY PROVISIONS Subtitle D (Sections 10638(4)).

- b. Being required to recruit trainees, Investigators, or other researchers to enroll in such program, position or activity;
 - c. Establishing a laboratory or company, accepting a faculty position, or undertaking any other employment or appointment in a foreign country or with an Entity based in, funded by, or affiliated with a foreign country when such activities are in violation of the standard terms and conditions of a U.S. federal Research and development award;
 - d. Being unable to terminate the foreign talent recruitment program contract or agreement except in extraordinary circumstances;
 - e. Being limited, either by funding or effort related to the foreign talent recruitment program, in the capacity to carry out a Research and development award or being required to engage in work that would result in substantial overlap or duplication with a U.S. federal Research and development award;
 - f. Being required to apply for and successfully receive funding from the sponsoring foreign government's or foreign Entity's funding agencies with the sponsoring foreign organization as the recipient;
 - g. Being required to omit acknowledgment of the recipient institution with which the individual is affiliated, or the U.S. federal agency sponsoring the Research and development award, contrary to the institutional policies or standard terms and conditions of the federal Research and development award;
 - h. Being required to not disclose to the U.S. federal agency or employing institution the participation of such individual in such program, position or activity; or
 - i. Having a conflict of interest or conflict of commitment contrary to the standard terms and conditions of the U.S. federal Research and development award; and
2. A program that is sponsored by:
- a. A foreign country of concern³ or an Entity based in a foreign country of concern, whether or not directly sponsored by the foreign country of concern;
 - b. An academic institution or a foreign talent recruitment program on the list developed in the National Defense Authorization Act⁴.

Organizational Conflict of Interest ("OCI"): An OCI is a circumstance in which an institution (or an Investigator at the institution), may have unequal access to information or the existence of a conflicting role(s) that might bias judgement in the proposal for, or conduct of, Research. The existence of an OCI may mean an Investigator is unable or potentially unable to render impartial assistance or advice to the sponsor, potentially biased in the identification or selection of sub-contractors, the objectivity in performing the Research is or might be impaired, or may have an unfair competitive advantage in applying for Research funding.

Outside Activities: Any activity, paid or unpaid, that is related or similar to an Investigator's Institutional Responsibilities and is performed outside the University (excluding professional service). This includes, but is not limited to, outside employment, consulting, advising, personally reimbursed or Sponsored Travel,

³ The list of "foreign countries of concern" includes the People's Republic of China, the Democratic People's Republic of Korea, the Russian federation, the Islamic Republic of Iran, or any other country deemed to be a country of concern as determined by the Secretary of State. For questions as to whether a specific country or entity is "of concern" please contact Research Security and Ethics: researchsecurity@uc.edu.

⁴ The full reference for these lists can be found under section 1286(c)(8) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 2358 note; Public Law 115-232).

conducting Research outside the University, roles on outside boards, financial interests, gifts, foreign government affiliations (any academic, scientific, professional, or institutional affiliation with a foreign government or Entity, including participation in a Foreign Talent Recruitment Program), and other compensated or uncompensated activities or interests.

Outside Activity Report (“OAR”) refers to the disclosure form that is required annually for Investigators and any non-University personnel who act as an Investigator at the University. Investigators should disclose all personal Financial Interests and those of their Immediate Family, regardless of value, that appear to be related to the Investigator’s Institutional Responsibilities.

Remuneration refers to salary and any payment for services not otherwise identified as salary, including but not limited to consulting fees, honoraria, and outside employment.

Research means an 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) as well as product development research (e.g., diagnostic test or drug). As used in this Policy, the term includes, but is not limited to, any such activity for which sponsored funding is available from a U.S. federal, state or local government agency, or a public or private Entity, through a grant, contract or cooperative agreement (e.g., a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, research resources award, training grant, or outreach award).

Senior/Key Personnel refers to the project director or principal investigator and any other person identified as senior or key personnel in the grant application, progress report, or any other report required to be submitted by applicable law, regulation, or policy.

Significant Financial Interest (“SFI”) is a Financial Interest of one or more of the following interests of an Investigator or the Investigator’s Immediate Family that **reasonably appears to be related to an Investigator’s Institutional Responsibilities:**

1. **For publicly traded Entities**, if the value of any Remuneration received from the Entity in the twelve months *preceding* the disclosure *combined* with the value of any Equity Interest of the Investigator in the Entity as of the date of disclosure, when aggregated, exceeds \$5,000;
2. **For non-publicly traded Entities** (including but not limited to private “start-up” companies, closely held corporations, partnerships, or sole proprietorships), if either:
 - i. The value of any Remuneration received from the Entity in the twelve months *preceding* the disclosure, when aggregated, exceeds \$5,000, **or**
 - ii. The Investigator holds **any** Equity Interest (i.e., there is not a *de minimis* amount for Equity Interests in a non-publicly traded Entity) in the Entity. Investigators are required to disclose in the OAR and in sponsor requirements, as applicable, venture and/or other capital financing and additional information about the investors, if known;
3. Income from intellectual property rights and interests (e.g., patents, copyrights, trademarks), not paid by the University, that exceeds \$5,000 in the previous twelve months; or
4. All reimbursed or Sponsored Travel exceeding \$5,000 from an Entity in the twelve months *preceding* disclosure; however, travel that is reimbursed or sponsored by a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a research institute that is

- affiliated with an American institution of higher education does **not** need to be disclosed as an SFI.
5. Participation in an FTRP.

The term “Significant Financial Interest” does not include the following types of Financial Interests:

1. Salary, wages, or other compensation for work paid by the University, provided that such salary, wages, or other compensation was not routed to the University by an Entity and intended for the Investigator at the direction of the Investigator in order to avoid disclosure as required by this Policy;
2. 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;
3. Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, an American institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American institution of higher education;
4. Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, an American Institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American institution of higher education; or
5. Salary, wages, or other compensation earned through employment with University of Cincinnati Physicians, Inc.

Sponsored Travel means travel that is paid for on behalf of an Investigator and not reimbursed to the Investigator directly.

Subrecipient is a legal Entity that receives a Subcontract from a pass-through Entity to carry out a portion of a sponsored program. A Subrecipient has responsibility for programmatic decision making; has its performance measured in relation to whether objectives of a programmatic scope of work were met; and is responsible for adherence to applicable sponsored program requirements as specified in the sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through Entity.

University refers to the University of Cincinnati, including but not limited to colleges, departments, units, and administrative offices.

UC Official means the University President, Vice Presidents (“VP”), Deans, Department Chairs, Division Directors, members of the Technology Transfer Office, and UC’s Conflict of Interest Office, and/or 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 FCOI arise when Investigators have Financial Interests, such as outside professional financial relationships that reasonably appear to be related to the Investigator’s Institutional Responsibilities. While these instances do not necessarily imply wrongdoing, the perception that such incentives might adversely affect Research objectivity, Investigator decision-making, and the protection of human subjects, requires that Outside Activities be disclosed and FCOIs appropriately managed. A disclosure that is considered a potential FCOI 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/or applications or proposals for Research funding.

A. Disclosure

Investigators at the University, and any non-University personnel who act as an Investigator, are required to disclose all Outside Activities and Financial Interests on their OAR (as required by University Board Rule 30-21-01). All Investigators are required to complete the OAR annually and within thirty (30) days of acquiring an Outside Activity. All new University employees are required to complete the OAR within the first thirty (30) days 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 Investigator and their Immediate Family that could appear to be reasonably related to the Investigator's Institutional Responsibilities. An Investigator who has not submitted an OAR or whose OAR has expired will not be permitted to conduct Research or submit new grant applications until a current OAR has been submitted. Thus, all Investigators should disclose in a timely manner according to this Policy, so they do not delay the submission of funding applications.

All completed OARs are first routed electronically to the Investigator's Department/Unit head or immediate supervisor for review. Once Department/Unit head review is complete, the disclosure will be routed to the College Dean/VP for review and approval. Disclosures containing potential SFI related to the Research will be reviewed by the Conflict of Interest Office prior to Research expenditure.

In addition, when sponsor terms require it, Investigators may be asked about additional relationships or activities that create other potential Organizational Conflicts of Interest⁵ with respect to procurement decisions and/or the University's ability to 1) render impartial assistance to the government, 2) perform work under an awarded contract in an objective way, or creates an unfair competitive advantage for the University in seeking funding. Required disclosures may include, but are not limited to, instances of providing Advisory and Assistance Services (A&AS) or Systems Engineering and Technical Assistance (SETA) to U.S. federal agencies.

B. Conflict of Interest Committee

The COIC is a standing faculty committee, designated with the responsibility to provide an independent peer-reviewed assessment of personal Financial Interests reported by Investigators. See University Board Rule 10-17-08 for committee appointment and composition. The COIC, in partnership with the COI Officer, shall identify and manage Financial Conflicts of Interest of Investigators as they relate to research. Any Conflicts of Commitment identified may be referred to the appropriate UC Official but the review and management can be assisted by the COI Officer and/or the COIC.

C. FCOI Review and Determination

The COI Officer is responsible for (i) reviewing all SFI disclosed in order to determine whether the SFI is related to Research, and if so related, (ii) referring SFI disclosures to the COIC to determine whether the SFI is a FCOI (unless the COIC has determined that the COI Officer can make this decision). The Vice President for Research ("VPR") and Deans may refer SFI disclosures (and other matters) to the COI

⁵ Note that the Department of Energy's Interim Policy on Conflict of Interest cites 2 CFR 200.318(c)(2) in the definition of Organizational Conflict of Interest, which is a procurement standard. Other agencies often cite 48 CFR Subpart 9.5 (Federal Acquisitions Register; FAR) in their definition of Organizational Conflict of Interest. This section acknowledges both definitions, and additional, agency-specific requirements for disclosure.

Officer and to the COIC for review and recommendation.

1. **Related to Research:** A SFI will be considered related to Research if the SFI could be affected by the Research, or if the SFI is in an Entity or belongs to an individual whose Financial Interest could be affected by the Research. The COI Officer may seek the input of the Investigator and/or their Department/Unit head to determine whether the SFI is related to Research. The COI Officer will refer SFI disclosures related to Research to the COIC for review and determination of whether a potential FCOI is present. Provided, however, that the COIC is authorized to delegate to the COI Officer its authority to determine whether an SFI constitutes an FCOI, the COI Officer may determine whether the SFI constitutes an FCOI without referral to the COIC.
2. **FCOI Determination:** The COIC (or the COI Officer operating under authority granted by the Committee) will determine whether the SFI *could* directly and significantly affect the design, conduct, and/or reporting of related Research. If the Committee and/or COI Officer find that an FCOI exists, then they will also determine whether the FCOI will be managed or eliminated prior to the expenditure of funds for the related Research.
3. **New SFI:** If, in the course of ongoing Research, an Investigator who is new to the Research project discloses an SFI, or an existing Investigator discloses a *new* SFI, the COI Officer will review the SFI, and, if the SFI is determined to constitute a potential FCOI, the COIC will be consulted. If an FCOI is identified, a **Conflict Management Plan (“CMP”)** will be implemented within sixty (60) days of the date of disclosure. If, in the course of an ongoing Research project, an Investigator discloses an SFI that was *not disclosed in a timely manner* as required by this Policy (see Section A above), the COI Officer will review the SFI, and consult with the COIC if the SFI appears related to the Research resulting in a FCOI requiring management within sixty (60) days of the date of the disclosure. *See Noncompliance section below for more details on failure to properly disclose according to this Policy.*

If human participants are involved in the Research related to SFI, the COI Officer will refer the SFI to the Institutional Review Board (“IRB”) Subcommittee on Conflicts of Interest for FCOI determination. If the SFI is determined to constitute an FCOI, the IRB Subcommittee on Conflicts of Interest will implement FCOI management, requiring protocol-specific safeguards per the IRB’s Guidelines and Procedures for Evaluation and Management of Conflicts of Interest in Human Subjects Research. The COIC and IRB Subcommittee on Conflicts of Interest may jointly implement safeguards to protect data integrity and human participant safety and wellbeing, respectively, in one *combined* CMP.

D. Management

If the COIC, the COI Officer, or the IRB Subcommittee on Conflicts of Interest determine that an FCOI exists and can be managed, the Investigator will be asked to complete a CMP, which requires specific details about the financial relationship, the Research related to the relationship, and the Investigator’s Institutional Responsibilities. The Investigator’s input regarding what actions should be included in the CMP will be considered by the COIC, the IRB Subcommittee on Conflicts of Interest, and/or COI Officer. The CMP will specify the actions that have been and/or will be taken to manage the FCOI. Examples of conditions and restrictions that may be implemented to manage a FCOI, either as a single condition or restriction, or as a combination of conditions and restrictions, and on either an interim or permanent basis, may include but are not limited to:

1. Public disclosure of the FCOI (e.g., in public presentations or publications of the related Research);
2. Disclosure of the FCOI to human participants, if applicable;
3. Appointment of an independent monitor capable and willing to take appropriate measures to protect the design, conduct, and reporting of the Research against potential bias resulting from the FCOI;
4. In instances in which students are involved in the Research, what steps will be taken to protect the students' academic progress, intellectual property interests, and/or welfare (e.g., appointment of an independent monitor for academic and research purposes, independent monitor for thesis/dissertation committee, responsible conduct of research training, etc.);
5. Modification of the Research plan;
6. Change of senior/key personnel or senior/key personnel responsibilities, or disqualification of senior/key personnel from participation in all or a portion of the Research, including interim disqualification of senior/key personnel from the Research between the date of disclosure and the completion of the University's review of the matter;
7. Reduction or elimination of the SFI (e.g., sale of an equity interest); and
8. Severance of the relationship resulting in the FCOI.

The COI Officer will communicate to the IRB summary information about the nature and amount of any SFI related to human participants in research, along with the COIC's findings, FCOI determination and any CMP approved by the COIC. Investigators conducting Research involving human participants should note that review of SFI and implementation of a CMP by the COIC does not constitute approval of the Research proposed. The IRB has final authority on whether the proposed Research should be approved and will not render its decision until after the IRB Subcommittee on Conflicts of Interest has reviewed the SFI and implemented a CMP and/or protocol specific safeguards. The IRB will consider the CMP, if any, in its final determination, and may include additional safeguards to the CMP if it deems them necessary for the protection and welfare of human participants.

The Investigator must document their adherence to the CMP by providing their signature. Once the Investigator has agreed to the terms outlined in the CMP, and the COIC approves the CMP, the COI Officer will request that the VPR review the CMP. The CMP is not final until the VPR reviews, approves, and signs the CMP in accordance with University Board Rule 10-17-08.

Funding for the related Research will not be released to the Investigator unless and until the CMP has been implemented and agreed to by the Investigator and the VPR. If funding has already been released, the COIC, the VPR, or the COI Officer may request that the funding be held pending the FCOI determination and the Investigator's agreement to the CMP.

In the event that an OCI is identified, a mitigation plan will be developed by the COIC and reviewed and approved by the VPR, per normal process, for submission with applications for financial assistance to the relevant federal agency if/when required. Other management and mitigation strategies may be implemented for an Investigator's other disclosed relationships that create apparent conflicts with their research depending on the nature and extent of the apparent conflict and/or the requirements of the sponsor(s).

E. Unmanageable Activities

Participation in a Maligned Foreign Talent Recruitment Program is prohibited for Investigators applying for

or receiving U.S. federal funding⁶. Investigators must disclose if they are foreign talent program members (malign or otherwise) for appropriate review in the OAR and to U.S. federal agencies⁷.

F. Required Updates to OAR

All SFI disclosures must be updated by Investigators in their OAR, at a minimum, on an annual basis and within thirty (30) days after any new SFI is discovered or acquired.

G. Required FCOI Training

The University will identify training appropriate to this Policy that must be completed by all Investigators at least once every four (4) years or immediately upon the occurrence of one of the circumstances listed below. The training will inform each Investigator of this Policy, the Investigator's responsibilities regarding disclosure of their SFI, and of the U.S. federal regulations pertaining to FCOI (e.g., 42 CFR § 50.601 *et seq.*). Immediate training for Investigators will be required under the following circumstances:

1. When the University makes revisions to this Policy that will impact an Investigator's responsibilities under this Policy;
2. When an Investigator is new to the University; and/or
3. When the University finds that an Investigator is not in compliance with this Policy or with their CMP.

H. Subrecipients

The University must apply relevant originating sponsor conflict of interest requirements to Subrecipients. Therefore, when required by the originating sponsor, the University must identify whether or not a Subrecipient has a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements. If a Subrecipient does not have a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements, in order to proceed with the University collaboration, the Subrecipient must agree to abide by this Policy relative to the Subrecipient Investigators and the specific Subrecipient research activity for the duration of that activity. The subrecipient agreement must incorporate terms that establish whether the conflict of interest policy of the University or that of the Subrecipient will apply to Subrecipient Investigators, and obligations of the Subrecipient relative to conflict of interest in either case.

V. Responsibilities

A. Investigators

1. Investigators are responsible for complying with the requirements of this Policy.
2. Investigators are responsible for making disclosures, both annually and as they arise (within thirty days), as outlined in this Policy. Prior approval must be received for new Outside Activities in accordance with University Board Rules 30-21-01 and 30-21-02.
3. Investigators are responsible for completing FCOI training at least once every four (4) years or otherwise as outlined above.
4. Investigators are responsible for providing information requested by the COIC and/or COI Officer in a timely manner so that the COIC and/or COI Officer may review and make a FCOI determination regarding the Investigator's disclosure.
5. Investigators are responsible for working with the COIC and/or COI Officer to establish reasonable

⁶ H.R. 4346 - 117th Congress (2021-2022): Chips and Science Act, TITLE VI – MISCELLANEOUS SCIENCE AND TECHNOLOGY PROVISIONS Subtitle D (Sections 10631).

⁷ H.R. 4346 - 117th Congress (2021-2022): Chips and Science Act, TITLE VI – MISCELLANEOUS SCIENCE AND TECHNOLOGY PROVISIONS Subtitle D (Sections 10631 and 10632).

safeguards that protect the integrity of their Research, the Investigators, and human subjects (if applicable).

6. Investigators are responsible for providing documentation of their agreement to abide by the CMP. Investigators are also responsible for abiding by all the terms, conditions, and actions set forth in the CMP. This responsibility carries with it the obligation to respond to requests for information from the COIC and/or COI Officer, and/or to attend meetings related to the University's responsibility to monitor compliance with this Policy, the applicable CMP (if any), and applicable U.S. federal regulations (e.g., 42 CFR § 50.601 *et seq.*).
7. Investigators not in compliance with this Policy, their CMP, if any, and/or U.S. federal FCOI regulations (42 CFR § 50.601 *et seq.*) and other sponsor requirements as applicable, are responsible for complying with all corrective actions, enforcement mechanisms and/or sanctions imposed by the University, subject to any appeal rights included in this Policy and/or relevant collective bargaining agreements, where applicable.

B. The University

1. The University will maintain this Policy, make it available publicly (as required by law or regulation), and ensure that it complies with all applicable U.S. federal FCOI regulations (42 CFR § 50.601 *et seq.*) and rules (National Science Foundation, Grant Policy Manual, Ch. 510, Conflict of Interests Policy [NSF 510], National Aeronautics and Space Administration [GIC 23-07], Department of Energy [2 CFR 200.112], and other sponsors as required).
2. The University will make FCOI training that complies with this Policy and all applicable U.S. federal FCOI regulations available to Investigators.
3. The University will provide all FCOI reports to Research sponsors as required by federal FCOI regulations (42 CFR § 50.604(h) and 50.605(b)) and rules (NSF 510), and all applicable sponsor terms and conditions, and/or as may be required by a CMP.
4. The University will implement enforcement mechanisms to ensure Investigator compliance with this Policy and U.S. federal FCOI regulations (42 CFR § 50.604(g) and (h)) and rules (NSF 510).
5. The University will maintain records relating to Investigator SFI disclosures as well as the University's review and determination for each disclosure, as required by U.S. federal FCOI regulations (42 CFR § 50.604(i)).
6. The University will make information relating to Investigator SFI disclosures and the University's review and determination for each disclosure available upon request to the sponsoring agency, as outlined in U.S. federal FCOI regulations (42 CFR § 50.605(a)(5)(i)-(iii) and rules (NSF 510).

VI. Noncompliance – Investigator Failure to Disclose or to Abide by CMP

When the monitoring results (or other instances) identify a potential failure to comply with University policies and processes governing conflicts of interest in Research, the COIC and COI Officer will assess the circumstances and determine whether the Investigator failed to comply and, if this is the case, the extent of the non-compliance. The COIC and COI Officer may discuss the compliance failure with the Investigator and/or others (which may include Internal Audit, Office of General Counsel, the Research Integrity Officer, and other UC Officials and mechanisms of investigational inquiry) to make their final recommendation.

For example, an Investigator is noncompliant if they fail to:

1. Report SFIs accurately, fully, and in a timely manner;
2. Complete mandatory training;
3. Provide additional information as requested by the COIC or COI Officer;

4. Comply fully and promptly with management plans or decisions of the COIC or COI Officer, subject to the reconsideration process set forth herein (below);
5. Update disclosures as required herein;
6. Report SFIs as required by Research sponsors; and/or
7. Report SFIs to the University and/or Research sponsors due to requirements by the foreign Entity to conceal or withhold confidential financial or other ties between the Investigator and the foreign Entity.

If the COIC or COI Officer have reasonable cause to believe that the Investigator has failed to comply with this Policy or an applicable CMP, then they will inform the Investigator of the basis for such belief and afford the Investigator an opportunity to explain the alleged compliance failure. The COI Officer, COIC and/or VPR are authorized to stop Research or hold Research funding in order to ensure compliance with this Policy, a CMP, and/or applicable U.S. federal FCOI regulations (see 42 CFR § 50.605(a)(1)(i)-(vii) and (a)(2)), rules (NSF 510), or other sponsor requirements. If the Investigator has no active, funded Research, the COI Officer and/or COIC will recommend other appropriate actions, including but not limited to disciplinary measures related to the Investigator's employment at the University, to the appropriate administrator, subject to any appeal rights included in this Policy and/or relevant collective bargaining agreements, where applicable.

Noncompliance Reporting

Noncompliance with a plan to manage or eliminate a FCOI related to U.S. federally-funded Research that appears to have biased the design, conduct, or reporting of such Research, shall promptly be reported to the appropriate Public Health Service Awarding Component (42 CFR § 50.605(a)(1)-(6)).

VII. Appeal: Requests for Reconsideration

An Investigator who disagrees with application of this Policy or with the decision of the COI Officer, COIC, or VPR may appeal the decision 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 Investigator. Please see University Board Rule 10-17-08 for additional information.

Related links:

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

30-21-01

30-21-02

30-21-03

HR 16.11

Phone Contacts:

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