

<b>ADMINISTRATIVE DIVISION</b>	RSCH Research
<b>POLICY NUMBER</b>	RSCH 1.06
<b>POLICY TITLE</b>	Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects
<b>SCOPE OF POLICY</b>	USC System
<b>DATE OF REVISION</b>	February 3, 2025
<b>RESPONSIBLE OFFICER</b>	Vice President for Research
<b>ADMINISTRATIVE OFFICE</b>	Office of Research

**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 under externally sponsored (e.g., Public Health Service [PHS] or National Science Foundation [NSF]) grants and cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

**DEFINITIONS**

**Investigator:** The principal investigator, project director, co-investigator, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of sponsored research (project) results, including collaborators and consultants.

**University Conflict of Interest Committee (COIC):** The Committee appointed by the Vice President for Research, in accordance with Part. E of this policy to review disclosures and relevant features of the sponsored project(s) and, based on the review, to recommend to the Reviewing Official any modifications necessary to manage any financial conflicts of interests related to the project.

**Financial Interest:** Anything of monetary value, whether the value is readily ascertainable (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, equity interests, intellectual property rights etc.).

**Malign Foreign Talent Recruitment Program:** A Malign Foreign Talent Recruitment Program is defined as:

- A. 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 individual—

1. engaging in the unauthorized transfer of intellectual property, materials, data products, or other nonpublic information owned by a United States entity 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;
2. being required to recruit trainees or researchers to enroll in such program, position, or activity;
3. 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 if such activities are in violation of the standard terms and conditions of a federal research and development award;
4. being unable to terminate the foreign talent recruitment program contract or agreement except in extraordinary circumstances;
5. through funding or effort related to the foreign talent recruitment program, being limited in the capacity to carry out a research and development award or required to engage in work that would result in substantial overlap or duplication with a federal research and development award;
6. being required to apply for and successfully receive funding from the sponsoring foreign government's funding agencies with the sponsoring foreign organization as the recipient;
7. being required to omit acknowledgment of the recipient institution with which the individual is affiliated, or the Federal research agency sponsoring the research and development award, contrary to the institutional policies or standard terms and conditions of the Federal research and development award;
8. being required to not disclose to the Federal research agency or employing institution the participation of such individual in such program, position, or activity; or
9. having a conflict of interest or conflict of commitment contrary to the standard terms and conditions of the Federal research and development award; and

B. a program that is sponsored by:

1. a foreign country of concern or an entity based in a foreign country of concern, whether directly sponsored by the foreign country of concern.
2. an academic institution or a foreign talent recruitment program on the list developed in the National Defense Authorization Act.

**Senior/Key Personnel:** The PD/PI (Program Director/Principal Investigator) and any other person identified as senior/key personnel by the university in the grant application, progress report, or any other report submitted to the sponsoring agency.

**Significant Financial Interest (SFI):** Financial Interest held by an Investigator, or the Investigator's spouse or dependent children that reasonably appear to be related to the Investigator's Institutional Responsibilities and that consists of one or more of the following:

- Remuneration including, but not limited to salary, consulting fees, honoraria, and paid authorship received from a publicly traded company during the 12-month period preceding the date on which an Investigator is making a disclosure, and/or an equity interest (e.g. stock, stock options or other ownership interest) held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the equity interest as of the date of disclosure, exceeds \$5,000; or
- Remuneration received from a non-publicly traded company during the 12-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000; or
- Any equity interest in a non-publicly traded company or business, regardless of value; or
- Payments or royalties related to intellectual property rights and interests (e.g. patents and copyrights), upon receipt of income from a single source exceeding \$5,000 other than USC, or,
- Reimbursed travel or travel expenses exceeding \$5,000 received over the preceding 12 months on an Investigator's behalf related to his/her institutional responsibilities, including circumstances when the exact monetary value of the travel is not readily available. This disclosure requirement does not apply to travel that is reimbursed by a U.S. Federal, state or local government agency, a U.S. institution of higher education, academic medical center or research institute that is affiliated with a U.S. institution of higher education.

Significant Financial Interest does not include:

- An employee's salary or royalties or other remuneration paid by the university and/or the South Carolina Research Foundation if the Investigator is currently employed or otherwise appointed by the Institution; or
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state or local government agency located in the United States, a United States Institution of higher

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

- 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.

**Institutional Responsibilities:** Investigator's professional obligations carried out on behalf of the university, involving the Investigator's expertise. Examples include activities such as research, research consultation, teaching, professional practice, participation in purchasing decisions, evaluating products on behalf of the university, university committee memberships, and service on panels such as institutional review boards or regulatory oversight committees.

**Financial Conflict of Interest (FCOI):** When applied to an Investigator, Financial Conflicts of Interest occur in situations in which an Investigator's Significant Financial Interest is determined to be related to the sponsored funded research (e.g., National Institutes of Health [NIH] or NSF) and could directly and significantly affect the design, conduct or reporting of research or compromise, or could appear to bias, his or her professional judgment regarding the design, conduct or reporting of research..

**University Reviewing Official (RO):** The official designated by the university to solicit and review disclosures of significant financial interests and reasonably determine whether an Investigator's reported financial interest is related to the sponsored research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and, if so related, whether the significant financial interest is a FCOI (i.e., the SFI could directly and significantly affect the design, conduct, or reporting of the funded research).

#### **POLICY STATEMENT**

The university has published high standards for faculty conduct, including the conduct of research, in the University of South Carolina (USC) Faculty Manual and its Policies and Procedures. All USC Investigators are expected to carry out research consistent with these standards.

Even when these high standards have been met, conflicts of interest or perceptions of conflicts may still occur when there is a convergence of an Investigator's private interests with his or her 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 gain. Such conflicts are common in modern research universities and do not impugn the character or actions of any individual.

Therefore, it is the policy of the university that any Investigator (that is, any university employee or sub-recipient investigators responsible for the design, conduct, or reporting of a sponsored project at the university) is required to disclose significant financial interests related to his/her institutional responsibilities pursuant to circumstances specified by this policy.

When the university reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of the research, the university will take steps either to manage or to eliminate any financial conflicts of interest.

This policy supplements, but does not supplant, the university policy [ACAF 1.50 Outside Professional Activities for Faculty](#).

## **PROCEDURES**

This policy shall apply to research grant and cooperative agreement projects sponsored by various federal agencies, including but not limited to, PHS awarding components (e.g., the NIH) and the NSF. As described below, the university may elect to apply the disclosure requirements of this policy to other externally sponsored projects and certain university-managed programs. Application of this policy will be expanded to other extramural sponsors as necessary to comply with requirements imposed by those sponsors. Information regarding specific institutional and sponsoring agency requirements is located at [Office of Research Compliance](#).

### **A. Federal Disclosure Requirements:**

This policy implements federal requirements pertaining to “Objectivity in Research for which Public Health Service Funding is Sought” 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 Subpart F and 45 CFR Part 94. This policy also implements federal requirements contained in the National Science Foundation’s “Investigator Financial Disclosure Policy” and other policies as may be promulgated by federal funding agencies. These agencies require the university to maintain an appropriate written policy on Investigator financial conflict of interest as a condition for receiving federal grants and research contracts. These federal requirements are applicable to all proposals for extramural awards submitted to these federal agencies. This policy implements the regulatory requirements provided in the grant and cooperative agreement regulation 42 CFR Part 50 Subpart F.

### **B. Other Sponsored Programs and Projects:**

The university may elect to apply the disclosure requirements of this policy to all or selected other externally funded programs. The applicability of this policy to such programs requires the joint approval of the vice president for research and the provost.

### **C. Training**

Investigators involved in research funded by sponsors subject to this Policy must complete the required financial conflict of interest training before engaging in research and every four years thereafter. The university may require immediate training if an investigator is new to the university, is found to be out of compliance, or if the FCOI policy is revised in a way that affects the requirements of investigators. Such training must include the following topics.

1. Informing the Investigator about the institution’s FCOI policy.

2. The Investigator's responsibility to disclose SFIs per this policy and the relevant regulations.

#### D. Disclosure Requirement

Each Investigator must disclose his/her known SFI's (including those of the Investigator's Immediate Family) that are related to the Investigator's Institutional Responsibilities performed on behalf of the university (e.g., research, research consultation, teaching, etc.), In determining whether a financial interest must be disclosed, the Investigator shall consult the definition of SFI within this policy and, if in doubt, resolve in favor of disclosure.

1. **Disclosure for each Proposal Submission:** At the time of submitting a new proposal, an Investigator must have completed their annual financial disclosure in the prescribed university system. The university will not submit a proposal until such a disclosure is completed. The proposal will be reviewed to determine if a disclosed SFI constitutes a FCOI that needs to be managed.
2. **Changes in SFI:** An updated disclosure shall be completed and filed within thirty (30) days of an Investigator acquiring or discovering a new reportable SFI. For Investigators on an existing covered project, new or newly identified SFIs will be reviewed to determine if an FCOI exists, create a management plan as appropriate and, if necessary, report the FCOI to the sponsor within 60 days of identifying an FCOI.
3. **New Investigators:** If research is ongoing and an Investigator newly participating in the project discloses an SFI related to their institutional responsibilities, the University will within 60 days review the SFI to determine if the SFI is related to the research and is an FCOI per the criteria, develop a management plan, and report the FCOI to the sponsor.

#### E. University Conflict of Interest Committee (COIC)

The Vice President for Research (VPR) shall appoint a University Conflict of Interest Committee (COIC). The voting membership of the committee will consist of the following: five members from the Columbia campus who hold faculty appointments and who represent a reasonable cross section of the academic disciplines that are involved in scholarly research. The Vice President for System Affairs shall appoint a minimum of two members from the Comprehensive and Regional campuses. Voting members are appointed to serve staggered three-year terms.

The COIC will have as permanent non-voting members representatives from the following administrative units/divisions, General Counsel, Research Compliance, Human Resources, Technology Commercialization, and Provost. The chair of the University Committee shall be appointed by the VPR.

The COIC shall provide advice and recommendations on decisions related to conflicts of interest and commitment for Investigators involved in the design, conduct or reporting of sponsored research at the university.

#### F. Review of Disclosures

Disclosures shall be reviewed by the RO and/or the COIC to determine whether any reported SFI constitutes a FCOI.

A FCOI exists when the university, through its RO, reasonably determines that the SFI:

- is related to the sponsor-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and
- could directly and significantly affect the design, conduct, or reporting of the sponsored research/project. “Significantly” in this statement means the financial interest would have a material effect on the research.

Based on information provided in the disclosure, the RO and/or the COIC 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 RO's or Committee's action and the project can proceed without further review.

If the university RO reasonably concludes that a project could have an impact on financial interest and that the financial interest could affect directly and significantly the design, conduct or reporting of the project, the basis for the finding will be documented and the RO, working with the COIC will determine the actions that are necessary to manage the FCOI.

#### G. Management or Elimination of Investigator Financial Conflicts of Interest

When it is reasonably determined that an Investigator has a FCOI, the RO and/or COIC will recommend implementing a plan to manage the financial conflict of interest.. Investigators may be consulted regarding conflict management strategies. Examples of conditions or restrictions that may be imposed to manage or eliminate conflicts of interest include but are not limited to:

1. Public disclosure of financial conflicts of Interest(s) when presenting, publishing, or reporting the research.
2. Disclosure of financial interests to co-investigators and research personnel working on the project.
3. For projects involving human subject research, disclosure of financial conflicts of interest to the IRB and directly to subjects.

4. 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.
5. Modification of the research or project plan.
6. Disqualification of Investigator(s) from participation in all or a portion of the project.
7. Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
8. Severance of relationships that create financial conflicts.

Alternatively, the RO and/or COIC may recommend that the project not be undertaken by the university if it is determined that the conflicts cannot be managed satisfactorily.

The review of the disclosure(s) and adoption of conditions or restrictions to manage or eliminate conflicts of interest must be completed prior to expending funds provided under the sponsored award and within 60 days of identifying an FCOI during the period of an award. When required, the RO will report the FCOI to the sponsoring agency. This includes submitting initial, annual and revised FCOI reports for the university's investigators and those of its subrecipients.

The university will monitor Investigator compliance with a management plan for the duration of the sponsored award or until the FCOI no longer exists during the period of performance of a sponsored award.

**Unmanageable Activities:** Participation in a Malign Foreign Talent Recruitment Program is prohibited for researchers applying for or receiving federal funding. Investigators must disclose if they are associated with a foreign talent program.

## H. Non-Compliance

Instances of noncompliance may subject the individual to disciplinary or remedial actions (e.g. mandated training). Disciplinary action for noncompliance will be administered according to applicable university disciplinary policies and procedures

The following are examples of noncompliance with this Policy:

1. Failure to submit a timely SFI disclosure.
2. Submission of an incomplete, erroneous, or misleading SFI disclosure.
3. Failure to comply with prescribed management plans.

For instances of noncompliance involving PHS-funded research, and certain other sponsors, whenever a FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI, failure by the University to review or manage such a FCOI, or failure of an Investigator to comply with the conditions of a financial conflict of interest management plan, the university must conduct a retrospective review of the Investigator's PHS-funded research activities performed during the period of noncompliance to determine if there is bias in the design, conduct, or reporting of the research resulting from the FCOI. The retrospective review must be completed within 120 days of the USC's determination of noncompliance. The retrospective review will be documented, and such documentation will include, but may not be limited to, the project number and title, the Project Director(s) or Principal Investigator(s), name of the Investigator with the FCOI, entity name, reason(s) for the retrospective review, and the methodology followed, findings and conclusions of the review. If bias is found during the retrospective review, the university must promptly notify the sponsor, take corrective action, update any previously submitted reports, and submit a mitigation report that addresses the impact of the bias on the research and the University's plan of action to eliminate or mitigate the effect of the bias.

#### Clinical Research Requirements

Instances of noncompliance noted above that involve PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the FCOI in each public presentation of the results of the relevant research and request an addendum to previously published presentations of the relevant research.

#### I. Sanctions

Failure to file a complete Disclosure of Significant Financial Interests or to otherwise fail to comply with this policy will be grounds for disciplinary action pursuant to the university policies related to faculty conduct or other applicable employee disciplinary policies.

Federal sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards if there is a failure to comply with applicable regulations on disclosure and management of conflicts of interest related to federally sponsored projects.

#### J. Responsibilities and Administration

The Provost, Vice President for Research and deans within their respective areas of responsibility, shall implement this policy. Implementation shall be monitored by the vice president for research or designee, in consultation with the provost.

##### 1. Subrecipient Requirements

The university will establish, via written agreement, that subrecipients will follow this FCOI policy, or certify adherence to their own regulatorily compliant FCOI policy. Subrecipient agreements will require the subrecipient to report identified FCOIs in a manner that allows the university to report FCOIs to sponsors. Alternatively, subrecipient agreements will include a requirement to solicit, review, and submit subrecipient

Investigator disclosures to the university to enable it to identify, manage and report identified FCOIs to relevant sponsors.

2. Records Maintenance Requirements

Records regarding Disclosures, RO's determinations, COIC recommendations, and university 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. Public Accessibility Requirements

Information concerning identified FCOIs held by senior/key personnel will be publicly accessible including the minimum elements as required by regulation at 42 CFR 50.604(a). This information will be made available within five business days of a written request and remain available for three years from the date the information was most recently updated.

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.

**RELATED UNIVERSITY, STATE AND FEDERAL POLICIES**

[ACAF 1.50 Outside Professional Activities for Faculty](#)

[BTRU 1.18 Conflicts of Interest and Commitment](#)

[RSCH 1.10 Prohibition on Participation in Malign Foreign Talent Recruitment Programs](#)

**HISTORY OF REVISIONS**

<b>DATE OF REVISION</b>	<b>REASON FOR REVISION</b>
August 13, 2012	New policy approval
May 31, 2014	This policy was revised to include certain projects that are required to provide disclosure of related financial interest according to accepted university procedures.
February 3, 2025	Policy revised to include additional details on the COIC, streamline and clarify language throughout.