

Financial Conflict of Interest in Research

Applies to: *Faculty (including part-time and visiting faculty), postdoctoral scholars, academic staff, staff, and students (including graduate/undergraduate student workers and graduate assistants) employed by the University of Southern California and including those working for Keck Medicine of USC (“USC Employees”). This policy continues to apply to individuals who are on sabbatical or other leaves, or who are visiting other institutions.*

1. POLICY

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2. Policy Purpose

The purpose of this policy is to promote the highest ethical standards in situations where financial conflicts of interest may occur in the conduct of research.

The University of Southern California (“USC”) encourages its faculty, staff, and students to participate in meaningful professional relationships with industrial and other private partners. These partnerships are established for mutually beneficial reasons and often produce knowledge and technology that will help to meet societal needs.

In certain circumstances, significant financial interests can create or appear to create financial conflicts of interest in research. While having a financial conflict of interest in research does not imply wrongdoing or inappropriate activity, financial conflicts on interest in research do require review and management to ensure that the conflict does not improperly influence, or appear to improperly influence, how USC research is proposed, conducted, or reported. Transparency is the cornerstone of effective conflict oversight and management. Many times, disclosure itself minimizes a perception of bias in the conduct of research. It is therefore critical that all outside significant financial interests be disclosed promptly, fully, and thoroughly, in advance, in the manner provided in this policy. This policy explains the process for investigators to disclose significant financial interests and the methods by which they are reviewed and managed by the university.

3. Scope and Application

This policy applies to all university faculty members (including part-time and visiting faculty), staff and other employees, and students (including postdoctoral fellows) who propose, conduct, or report research on behalf of the university, regardless of funding source. This policy applies to all sponsored projects, including government and non-government funded projects (such as industry or foundation sponsors), university funded projects, gift funded projects, clinical trials, and also to unfunded research projects.

Investigators are not permitted to begin any research activity until they have disclosed all outside significant financial interests and have received a written determination from the Senior Vice President of Research and Innovation (SVPRI) as to how to manage any financial conflicts of interest in research identified by USC.

Special care must also be taken when students or trainees are involved with research where an actual or apparent financial conflict of interest exists so that academic progress is not impeded or affected by a faculty member or supervisor's conflict of interest.

4. Definitions

Term	Definition
Close Relation	Spouse, domestic partner, intimate partner, or dependent child of an investigator or research personnel. Please note that this definition follows the National Institute of Health definition and differs from the definition under the Conflict of Interest and Commitment policy.
Conflict of Commitment	Arises when a USC Employee undertakes a role (paid or unpaid) outside of USC that interferes, appears to interfere, or has the potential to interfere with the USC Employee's ability to perform core job responsibilities and commitments to USC. For more on conflicts of commitment please consult the Conflict of Interest and Commitment policy.
Conflict of Interest Review Committee ("CIRC")	The CIRC, chaired by the Senior Vice President of Research and Innovation (SVPRI) or their designee, is charged with reviewing Financial Conflicts of Interest (FCOIs) and formulating recommendations to manage, reduce, or eliminate financial conflicts of interest. The CIRC also assists in the review of SFIs to determine when a SFI creates a FCOI. The CIRC consists of faculty members appointed by the SVPRI, a representative from the Office of Culture, Ethics and Compliance, a representative from the USC Stevens Center for Innovation (non-voting), a representative from the Institutional Review Board (IRB) or the Human Research Protection Program (HRPP), an attorney from the Office of General Counsel (non-voting), a representative from the Department of Contracts and Grants (non-voting), and such other representatives as may be determined by the CIRC.
diSClose	USC's on-line disclosure system which is used to submit disclosures of significant financial interests, as well as conflicts of interest covered under other policies.
Financial Conflict of Interest in Research	A financial conflict of interest in research exists when the institution's designated official(s) reasonably determines that an investigator's significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of research.
Foreign Talent Recruitment Program	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

	<p>other documentation at issue.</p> <p>This does not include:</p> <ul style="list-style-type: none"> – Making scholarly presentations regarding scientific information not otherwise controlled under current law. – Participating in international conferences or other international exchanges, research projects or programs that involve open and reciprocal exchange of scientific information not otherwise controlled under current law. – Involvement in national or international academies or professional societies that produce publications in the open scientific literature that are not in conflict with the interests of USC. – Taking a sabbatical, serving as a visiting scholar, or engaging in continuing education activities such as receiving a doctorate or professional certification at an institution of higher education are not in conflict with USC. – Receiving awards for research and development which serve to enhance the prestige of USC (e.g., the Nobel Prize). – Academic collaborations with a foreign researcher where each side contributes to the project not otherwise controlled under current law.
Institutional Responsibilities	<p>An investigator's professional responsibilities on behalf of USC including, but not limited to, activities such as research, teaching, professional or clinical practice, and service including memberships on committees and panels such as Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards (DSMBs).</p>
Investigator	<p>The principal investigator, co-principal investigator, contact principal investigator, or co-investigator. Other persons are regarded as investigators if they have independent responsibility for some aspect of the design, conduct, or reporting of research.</p>
Malign Foreign Talent Recruitment Program	<p>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 of concern, or an entity based in, funded by, or affiliated with a foreign country of concern, in exchange for the individual doing one or more of the following activities:</p> <ul style="list-style-type: none"> 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 award; being required to recruit trainees or researchers to enroll in such program, position, or activity; establishing a laboratory or company, accepting a faculty position, or undertaking any other employment or appointment; being unable to terminate the foreign talent recruitment program contract or agreement except in extraordinary circumstances; being limited in the capacity to carry out a research and development award or required to

	<p>engage in work that would result in substantial overlap or duplication with a federal research and development award;</p> <p>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;</p> <p>being required to omit acknowledgment of your USC affiliation;</p> <p>being required to not disclose to USC or a federal research sponsor your participation in such program, position, or activity; or</p> <p>having a conflict of interest or conflict of commitment contrary to USC or a federal research sponsor.</p>
Research	<p>A systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral and social-sciences research or other scholarly activity in any discipline, whether or not it is funded.</p>
Research Personnel	<p>Any other USC faculty member (including part-time and visiting faculty), staff, other employees, and students (including postdoctoral fellows) who contribute to a research activity, whether or not the research is funded, and regardless of employment status (e.g., research associates, technicians, nurse coordinators, administrators, graduate assistants) who does not meet the definition of Investigator.</p>
Significant Financial Interest	<p>A Significant Financial Interest is a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities. These include:</p> <ul style="list-style-type: none"> – Remuneration received from, or equity interests (e.g. stocks, stock options, other ownership interests) held in, publicly traded entities that, alone or on combination, exceeds \$5,000 in the twelve month period preceding disclosure, including, or following the disclosure. The value of equity interests reported is as of the time of disclosure. – Remuneration received from non-publicly traded entities that exceeds \$5,000 in the twelve months preceding disclosure or following the disclosure. – Equity interests (e.g. stocks, stock options, or other ownership interests) held in non-publicly traded entities, regardless of value. – Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests. – Reimbursed or sponsored travel that exceed \$5,000 received in the twelve months preceding disclosure related to institutional responsibilities (with the exception of reimbursed or sponsored travel paid by a federal, state, or local agency located in the United States; a United States institution of higher education; or an academic teaching hospital, medical center, or a research institute that is affiliated with a United States institution of higher education). Disclosure must include the purpose of the trip, identity of the sponsor, the destination and the duration. – Holding a management role (paid or unpaid) that maintains significant decision-making

	<p>authority in an outside entity. Examples of management roles with significant decision-making authority include chief scientific officer, board member, founder, or any similar role.</p> <p>A Significant Financial Interest does not include the following types of interests:</p> <ul style="list-style-type: none"> – Salary, royalties, or other remuneration paid by USC to the investigator if the investigator is currently employed or otherwise appointed by USC, including intellectual property rights assigned to USC and agreements to share royalties related to such rights. – 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. <p>NOTE: Investigators must disclose to USC Significant Financial Interests received from any foreign entity, including foreign institutions of higher education.</p>
Student or Trainee Financial Conflict of Interest	<p>A student or trainee financial conflict of interest exists when a researcher has a financial interest in a company and retains a student, post-doc, or resident to provide services (paid or unpaid) that could benefit the company and any one of the following apply:</p> <ul style="list-style-type: none"> – The student is currently enrolled in the class of an investigator, research personnel, or close relation. – The investigator, research personnel or close relation supervises the student or trainee in an academic capacity. – The investigator, research personnel or close relation can influence the academic progress of the student or trainee. – The investigator, research personnel or close relation otherwise supervises the student or trainee as a research assistant or employee.

5. Policy Details

5.1 Duty to Disclose

Investigators and research personnel are responsible for identifying and disclosing Significant Financial Interests (SFIs) covered by this policy. Investigators and/or research personnel should evaluate their SFIs on an ongoing basis and disclose, promptly and in advance, any new SFIs. This responsibility arises when a new proposal is submitted; a new relationship is established with an outside entity; or when a prior relationship with an outside entity changes.

Investigators must submit an annual disclosure of SFIs related to their institutional responsibilities (regardless of whether the interest creates a Financial Conflict of Interest) when mandated by a research sponsor [e.g., the Public Health Services Agencies including the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA), or other federal agencies including the Department of Energy (DoE)], in accordance with the schedule established by the university. The university may also require disclosures at other times. Investigators who have or are seeking support from any sponsors who require an annual disclosure must have a current annual disclosure at the time of proposal submission and update their disclosure on an annual basis. If the investigator assumes a new SFI that has not been previously disclosed, or a

new investigator with an SFI joins an ongoing research project, the investigator must update his or her disclosure within thirty (30) days of discovering or acquiring the new SFI.

In the event there is subcontracted research from USC to an outside entity, all conflict identification, disclosure, and mitigation requirements will be flowed down to the subcontractor organization as required. Investigators are responsible for alerting the Office of Culture, Ethics, and Compliance if they become aware of a SFI maintained by a researcher at a subcontractor organization that has not been reported.

Investigators are responsible for confirming that research personnel under their supervision who are involved in proposing, conducting, or reporting research on the investigator's project identify and disclose any SFIs.

5.2 Review Process

Disclosed SFIs will be reviewed by USC's designated official(s). A financial conflict of interest exists if the designated official(s) reasonably determines that an investigator's SFI(s) could directly and significantly affect the design, conduct, or reporting of the research because:

1. The SFI is related to the 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
2. The SFI could directly and significantly affect the design, conduct, or reporting of research.

Identified financial conflicts of interest (FCOIs) will be reviewed by the USC CIRC. If the FCOI is found to be manageable, the university will require the implementation of a management plan designed to mitigate the conflict, as described below. If the university determines that the conflict cannot be effectively mitigated through the implementation of a management plan, the research will not be allowed to proceed unless the investigator eliminates the outside interest or activity giving rise to the conflict.

The CIRC will make a recommendation to the SVPRI on how to appropriately mitigate the FCOI in a way that preserves the integrity and objectivity of the research. Faculty must keep in mind that certain significant financial interests and outside activities may create a FCOI that cannot be effectively mitigated or managed.

Investigators and research personnel are not permitted to begin any research activity where an FCOI has been identified, until they receive a written determination from the Senior Vice President of Research and Innovation (SVPRI), or their designee, on how to manage it.

5.3 Sponsor Required Training and Reporting

When mandated, investigators must timely complete any required training imposed by research sponsors or the university. For example, all PHS-supported investigators must complete required training at least every four years, and immediately when any of the following circumstances apply:

- USC revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- An Investigator is new to USC; or
- USC finds that an Investigator is not in compliance with this policy, or any management plan imposed to mitigate the appearance of a conflict.

This training will include the requirements of this policy, including the responsibility to disclose SFIs, as well as any sponsor requirements as applicable.

As required by sponsors, USC will provide initial and ongoing reporting to sponsors (e.g. PHS) as required under federal regulations. This includes, reporting financial conflicts of interests prior to the expenditure of sponsor funds, or within 60 days of identification of a new FCOI during the period of an award as required by PHS.

5.4 Required Public Reporting

Prior to the expenditure of any funds under a NIH-funded research project, USC will make FCOI information available to the public in a written response within five business days of a request for any SFIs disclosed where:

- A. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- B. The Institution determines that the Significant Financial Interest is related to the NIH-funded research; and
- C. The Institution determines that the Significant Financial Interest is a **Financial Conflict of Interest**.

USC will provide the investigator's name, the investigator's title and role on the research project, the name of the entity in which the SFI is held, the nature of the SFI, and the approximate value of the SFI if it can be readily determined.

5.5 Additional Disclosure Responsibilities

Compensated Outside Research

Participation as a principal investigator, co-principal investigator, co-investigator, paid consultant, or paid staff member on sponsored projects at another entity (as distinct from research collaborations with other entities via a subcontract or subaward to USC) must be disclosed to the appropriate dean and the Senior Vice President for Research and Innovation (SVPRI) and are prohibited unless specially approved by the dean and the SVPRI or their designee.

Please note that, regardless of the nature of financial interest or covered outside activity, disclosure obligations for compensated outside research apply to domestic as well as foreign entities.

Foreign Financial Interests

Investigators must disclose to USC all foreign Significant Financial Interests. These include appointments (compensated or uncompensated) and any Significant Financial Interests (as defined in Section 4) received from any foreign entity, including foreign governments and foreign institutions of higher education.

5.6 Financial interests and outside activities that are not permitted

Certain types of financial interests and outside activities are not permitted because there is no feasible way to manage the Financial Conflict of Interest. These include:

- Participating in a Malign Foreign Talent Program when prohibited by a federal research sponsor. Malign Foreign Talent Programs are defined as talent programs sponsored by a foreign country of concern as defined by the United States Government or an entity in a foreign country of concern. These programs are of special concern as they can also require activities such as the recruitment of additional

researchers or unauthorized transfer of intellectual property, materials, data, or other nonpublic information developed with federal research funding.

- Participating in a paid “speaker’s bureau” (i.e., talks/presentations in which the topic(s) and/or content are provided by the company) for a research sponsor or a company that may benefit economically from the outcome of research.
- Incentive payments, bonus payments, finder fees, or any type of payment or incentive based on outcome, where the payment or incentive is made to the researcher or to research personnel relating to the proposal, conduct, supervision, or reporting of research (e.g., additional personal payments to investigators or research personnel who enroll a certain number of participants in a project within a certain period of time), or payment or incentive with respect to the evaluation of a product or service intended for a commercial market.
- Accepting personal gifts, gratuities, or special favors from an actual or prospective sponsor of an investigator’s research, other than occasional gifts or nominal or modest value (less than \$200 in value per occasion or isolated invitations to meals).

Maintaining a financial interest or engaging in an outside activity for a research sponsor who seeks to restrict publication of research results, other than reasonable delays of publication in order to protect proprietary rights (i.e., patent rights). This does not include restrictions on publication for reasons of national security and/or export control, if the requirements of USC’s International Collaborations and Export Controls policy are followed.

5.7 Required elements of financial conflict of interest management plan

When a Financial Conflict of Interest in Research is identified, all management plans implemented to mitigate the Financial Conflict of Interest will contain, at minimum, the following elements:

- All relevant publications, proposals, and presentations must contain a statement disclosing the Financial Conflict of Interest in Research.
- All informed consent documents in the context of human subjects research must disclose the Financial Conflict of Interest in Research. Conflicted investigators are not permitted to consent human participants.
- The investigator and/or research personnel and their close relations will not represent the university in any intellectual property or other contractual negotiations between USC and the outside entity.
- Investigators must notify all research personnel on the research project of the Financial Conflict of Interest in Research. In order to protect trainee (including students, post-docs, and residents) rights, the university may appoint a third-party monitor (e.g., faculty member, the Graduate School) to ensure the trainee is making timely academic progress and that their rights are otherwise protected

Management plans implemented to mitigate a FCOI may contain additional measures, including but not limited to:

- Recusal of the conflicted individual from data collection and/or data analysis for the relevant research project
- Referral to a supervisor or independent individual approved by the CIRC for monitoring or oversight

- Reduction of involvement or role for the conflicted individual for the relevant research project
- Termination of student involvement in the research project or appointment of an independent monitor
- Removal of the conflicted individual from the research project.
- Divestiture of relevant financial interests
- Severance of outside activities that pose a financial conflict of interest.

Certain types of FCOIs present scenarios where the potential for actual or perceived bias is great enough that research personnel must present compelling circumstances as to why the research should proceed despite the presence of the FCOI, and that may mandate the imposition of additional measures to mitigate the appearance of a FCOI, to include a determination that the research cannot proceed as proposed. These scenarios include:

- Equity interests held in a privately held research sponsor, unless the investigator provides verification that the equity interest is less than 10% of the outstanding stock or non-stock ownership of the sponsor.
- Publicly held equity interests in excess of \$50,000 in a research sponsor, except when the interest is maintained in an investment vehicle where the investigator or research personnel does not directly control the investment decisions made (e.g., mutual fund).
- Management roles in a research sponsor or entity with a financial interest in the research.

In the case of human subjects research, a justification of compelling circumstances is also required when:

- Receipt of consulting payments that total \$25,000 or more in any twelve-month period from a sponsor or a company that may benefit economically from the outcome of the research.
- Private equity interests, regardless of value.

5.8 Additional review

In cases where a significant financial interest disclosure also reveals a conflict of commitment, an additional review must also be undertaken as specified in the Conflict of Interest and Commitment policy applicable to all university employees.

6. Procedures

[Financial Conflict of Interest in Research Procedures \(including PHS specific requirements\)](#)

7. Violations

It is serious misconduct or neglect of duty for any individual subject to this policy to fail to observe any of its requirements, including but not limited to failure to make full disclosure of all SFIs through diSClose promptly, fully, and in advance; failure to observe the terms of a management plan; or engaging in a prohibited activity. Findings of violation by the appropriate CIRC will be referred for consideration of sanctions or corrective action according to the Faculty Handbook, Student Handbook, or staff policies.

8. Forms

<https://disclose.usc.edu/>

9. Responsibilities

POSITION or OFFICE	RESPONSIBILITIES
USC Employees	Identify and report potential Conflicts of Interest to the Office of Culture Ethics and Compliance using diSClose . Obtain necessary approval on reported Conflicts of Interest in Research and adhere to management of Financial Conflict of Interest in Research plans. Report any material changes in previously reported and approved Conflicts of Interest. Update disclosures promptly upon any changes to the research or financial interests disclosed.
Conflict of Interest Review Committee (CIRC)	The CIRC is charged with reviewing financial conflicts of interest (FCOI) and formulating recommendations to manage, reduce, or eliminate conflicts of interest. The recommendations are then presented for approval to the Office of Research. The CIRC also assists in the review of SFIs to determine when an SFI creates a FCOI.
Office of Culture, Ethics and Compliance	Provide guidance on requirements and applicability of this policy and the disclosure process. Present disclosures to the CIRC for review.
Office of Research	Appoint CIRC committee members. Approve management plans proposed by the CIRC.

10. Related Information

[USC's Conflict of Interest in Professional and Business Practices policy](#)

[Relationships with Industry policy](#)

[Cooperation with Compliance Investigations policy](#)

[Faculty Handbook](#)

[42 CFR Part 50 Subpart F, Promoting Objectivity in Research \(HHS FCOI regulation\)](#)

[Financial Conflict of Interest — NIH Guidance](#)

[Conflict of Interest Policies — NSF Grant Policy Manual](#)

[AAU Guidelines on Managing Conflicts of Interest](#)

[AAMC Guidelines on Managing Conflicts of Interest](#)

[Food and Drugs: FDA Guidance on Financial Disclosure by Clinical Investigators](#)

[USC's International Collaborations and Export Controls policy](#)

11. Contacts

Please direct any questions regarding this policy to:

OFFICE	PHONE	EMAIL
Office of Culture, Ethics and Compliance	(213) 740-8258	Compliance@usc.edu