

University of Southern California
Conflict of Interest in Research: Policy and Procedure

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1.0 **Introduction**

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

In recent years, however, the complexities surrounding apparent and actual conflicts of interest and commitment have increased as the number of collaborative relationships between academia and industry has grown. While the University strongly supports our collaborations with industrial and other private partners, there are several key values that call for protection from conflicts that may arise from these relationships:

Our commitment to educating students;

Our commitment to academic freedom;

Our commitment to advancing the range and depth of knowledge and understanding of the natural world and the human condition;

Our commitment to the safety of patients under our care and participants in research;

Our commitment to open and timely communication and dissemination of knowledge;

Our commitment to protect both the appearance and actual integrity and objectivity of research, instruction and public service; and

Our commitment to transfer University-developed knowledge to the private sector to fulfill one of the goals of federally funded research, by bringing the fruits of research to

the benefit of society.

Policy Objectives

The objective of this document is to provide an institutional policy that encourages the full professional development of Investigators through their research, while minimizing the risk of unacceptable behavior in potential conflict situations. This policy is intended to assist University investigators in managing real or perceived conflicts of interest.

This policy cannot regulate or eliminate all situations of conflict of interest, but is intended to enable faculty members to recognize situations that raise an appearance of impropriety and to ensure that such situations are properly reviewed and resolved. To this end, all USC faculty and staff members must disclose actual or perceived conflicts so that they can be managed appropriately. Disclosure will not necessarily restrict or preclude an individual's activities. Indeed, the problem is rarely a particular conflict itself – rather it is the question about what is done with conflict. In most cases, problems arise when the conflict is not made apparent, or when it is not assessed or managed.

Conflict of interest includes non-financial as well as financial conflicts, because non-financial interests can come into conflict with a researcher's primary commitment to maintain scientific objectivity just as financial interests may.

In compliance with federal regulations that became effective on October 1, 1995, the University requires investigators applying to the Public Health Service (PHS) or the National Science Foundation (NSF) for funding to disclose in writing any significant financial interests related to that proposal. This policy also covers all apparent and actual conflicts of interest or commitment related to research, regardless of the funding sources of the project. **Accordingly, all research will be treated the same, regardless of funding source, and will be managed by this conflict of interest policy.**

This policy supersedes the University of Southern California Conflict of Interest in Research: Policy and Procedures, dated September 20, 1995.

Links to relevant policies, regulations and other resources related to this policy are included in Section 7.0 of this policy.

2.0 Scope

This policy applies to all University faculty members (including part-time and visiting faculty), staff and other employees, (such as postdoctoral scholars) and students (including postdoctoral fellows and graduate students) 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),

clinical trials and also to unfunded research projects (such as departmental or school funded projects).

3.0 **Definitions**

3.1 Conflict of Interest

The term "conflict of interest" in this policy refers to situations in which financial or other personal considerations compromise, or have the appearance of directly and significantly compromising an individual's professional judgment in proposing, conducting or reporting research. The bias caused by such conflicts may affect collection, analysis, and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.

A faculty member, staff member or student is considered to have a conflict of interest when he or she, or that person's Close Relation (as defined below), possesses a financial or personal interest in an activity that involves his or her USC responsibilities relating to research.

Investigators and other individuals involved in research should consider not only situations that are unacceptable, but should also consider gray areas that might involve the appearance of conflict. The mere appearance of a conflict may be just as serious and potentially damaging as an actual distortion of objectivity. For every situation contemplated, there will be some variant that adds a new set of considerations. Although not an all-inclusive list, examples of apparent or actual conflicts of interest that should be disclosed under this policy include the following:

- Undertaking basic or clinical research when an Investigator or Close Relation of an Investigator has a supervisory, managerial (e.g., director, officer, scientific, technical or advisory appointment) or ownership interest in the research sponsor or licensee or in a company having an economic interest in the research (e.g., producing the product under evaluation);
- Any equity interests (e.g., stocks, stock options or other ownership interests) held by an Investigator or Close Relation of an Investigator in a research sponsor or licensee or in a company having an economic interest in the research. This does not include mutual, pension or other funds over which the investigator does not exercise control;
- Any incentive payments, bonus payments or finders fees relating to the proposal, conduct or reporting of research received or intended to be received by an Investigator or his or her staff members, regardless of the amount of

compensation or payments received (e.g., additional payments by research sponsors to Investigators or research staff who enroll a certain number of participants in a project within a certain period of time);

- Any consultant arrangements between an Investigator or Close Relation of an Investigator and an organization or individual having an economic interest in the Investigator's research, which when aggregated for an Investigator, his or her staff members, and their respective Close Relations (as defined below) from that particular research sponsor exceeds \$10,000;
- Accepting gifts, gratuities or special favors from the sponsor of an Investigator's research, which when aggregated for an Investigator, his or her staff members, and their respective Close Relations (as defined below) from that particular research sponsor exceeds \$10,000;
- Accepting honoraria, travel expense reimbursement or other reimbursements from the sponsor of an Investigator's research in addition to the amounts budgeted for the project, which when aggregated for an Investigator, his or her staff members and their Close Relations (as defined below) from that particular research sponsor exceeds \$10,000;
- Intellectual property rights (e.g., patents, copyrights or royalties from such rights) obtained by an Investigator or an Investigator's Close Relation from a research sponsor;
- Using USC resources (e.g., the name or logo, facilities, personnel, equipment, information) by an Investigator or Close Relation of an Investigator for personal or non-USC related business (other than incidental use);
- Using students or USC employees to perform services for a company in which an Investigator or Close Relation of an Investigator has an ownership interest or from which he or she receives any type of remuneration;
- Unauthorized use of confidential, privileged or proprietary information obtained in connection with one's research responsibilities;
- Any outside commitment that provides for intellectual or tangible property such as patent ownership or licensing to an organization other than the University;
- An agreement that restricts an Investigator's public reporting of the information developed by an Investigator under the agreement, or the existence of the agreement. In the case of a relationship with a commercial organization, an Investigator must ascertain whether there are requirements for confidentiality

that might compromise his or her fundamental rights of academic freedom or those of other faculty members, students or the University;

- Undertaking research that may impact the financial interest of a company that holds rights to intellectual property for which the investigator or a Close Relation is the inventor and the licensor is not the University;
- Purchasing, including subcontracting, from entities in which an investigator or Close Relation has a financial interest.

3.2 Conflict of Commitment

The term "conflict of commitment" in this policy relates to an Investigator's distribution of effort between his or her responsibilities to USC and his or her outside activities. For example, full-time faculty members are expected to devote their primary professional loyalty, time and energy to their teaching, research, service and clinical duties, as applicable. A conflict of commitment arises when outside activities interfere with the individual's obligations to USC. A conflict of commitment for purposes of this policy includes, but is not limited to:

Outside consulting activities by faculty members that exceed the permissible limits (i.e., an average of one day per week);

3.3 Investigator

The term "Investigator" means the principal investigator, co-principal investigator, and any other person at the University who substantively is responsible for the design, conduct, and reporting of research activities, funded, proposed for funding, or unfunded.

3.4 Close Relation

The term "Close Relation" means spouse, mutual financial dependent, significant other, or person in an intimate relationship, child, parent, or sibling (including in-laws and step-relations), grandparent, grandchild, niece or nephew, aunt or uncle or cousin.

4.0 **Principles**

4.1 USC faculty members, staff and students are expected to avoid actual or apparent conflicts of interest and conflicts of commitment that directly and significantly affect USC's interests related to proposing, conducting or reporting research; or otherwise compromise the objectivity and/or performance in carrying out USC responsibilities related to research, unless such conflicts are managed in accordance

with this policy.

4.2 Keys to preventing and resolving conflicting situations are full disclosure followed by peer review, close monitoring and conflict management. Full disclosure of relevant information is in the best interest of the institution, the Investigator, and his or her research staff members. It demonstrates good faith on the part of the Investigator and protects his or her reputation and that of the University. Disclosure will not necessarily restrict or preclude an individual's activities.

4.3 It is the ultimate responsibility of each Investigator to determine whether he or she or his or her Close Relation or any individual involved in proposing, conducting or reporting research on his or her project (e.g., research staff members, technicians, administrators, graduate assistants) has an apparent or actual conflict of interest or commitment as defined by this policy. It also is the responsibility of the Investigator to ensure that any apparent or actual conflicts of interest or commitment as defined by this policy of any of his or her research staff are disclosed and managed pursuant to this policy. The Investigator will be held responsible for failure to comply with this policy. **If in doubt concerning the possibility of a conflict arising from outside interests and activities, Investigators should consult with the Vice Provost for Research, the Office of Compliance or the Office of General Counsel for guidance.**

4.4 Prior to the expenditure of PHS or NSF funded awards, the University must report to the federal awarding agency the existence of a financial conflict of interest and assure that the conflict has been managed, reduced, or eliminated. Furthermore, if for any reason the University finds it is unable to satisfactorily manage a conflict of interest, then the federal funding agency will be informed promptly. The Vice Provost for Research or his or her designee is responsible for these reports.

4.5 Failure to report a conflict of interest, or refusal to cooperate in the management of a conflict of interest, constitutes misconduct and may be cause for disciplinary action. Possible violations of this policy include, but are not limited to, refusal to file the disclosure form or furnishing false, misleading, or incomplete information on the disclosure form. Sanctions for violations of this policy can range from administrative intervention to termination of employment or dismissal for cause, in accordance with applicable University policies, which for faculty, are published in the Faculty Handbook.

5.0 **Procedure**

5.1 Prior to commitment to a proposed external activity or financial or business relationship relating to one's research, informal discussion between the Investigator and the relevant Dean or Assistant Dean for Research is strongly encouraged to promote mutual understanding and to prevent avoidable conflicts from developing. The Dean or Assistant Dean for Research is strongly encouraged to discuss the matter with the Vice

Provost for Research.

5.2 Prior to or contemporaneous with submitting a research proposal, Investigators must certify with a "yes/no" declaration that they have read and understand this policy and that they will comply with any conditions or restrictions imposed by USC to manage, reduce or eliminate conflicts of interest. That certification will be requested in the following documents: (1) the Contracts and Grants Proposal Approval Record, which must be completed for all sponsored projects submitted to the Department of Contracts and Grants; (2) the Institutional Review Board initial and continuing review applications; and (3) the Health Research Association form for non-government funded projects conducted by Keck School of Medicine Investigators.

5.3 An Investigator who has a conflict of interest or a conflict of commitment, as defined above, must complete a "*Statement of Outside Interests Related to Research*," which discloses the apparent or actual conflict and requests the information needed for the University to manage the conflict. The "Statement of Outside Interests Related to Research" can be obtained from the Department of Contracts and Grants or downloaded from its Web site at: www.usc.edu/dept/contracts.

5.4 During the term of an award, if any new or previously undisclosed conflicts of interest arise, the "Statement of Outside Interests Related to Research" disclosure statement to the University must be initiated or updated, particularly if there is any significant change in personal, financial or fiduciary status.

5.5 Once the "Statement of Outside Interest Related to Research" form is completed, it must be submitted promptly to the Vice Provost for Research for further action. Such submissions may be provided in a sealed envelope marked, "Confidential." Investigators should make disclosures directly to the Vice Provost for Research for resolution, not to the sponsor. Alternatively, the completed form also can be submitted to any of the following departments, which will forward the information directly to the Vice Provost for Research on the Investigator's behalf:

Department of Contracts and Grants www.usc.edu/dept/contracts

Office of Compliance www.usc.edu/compliance

Assistant Dean of Research of the relevant school

5.6 The Disclosure Review Committee consists of faculty members appointed by the Provost's office, along with Contracts and Grants and Technology Licensing Office staff (*ex officio*), an attorney from the Office of General Counsel (*ex officio*) and the Executive Director of the Office of Compliance (*ex officio*). A current list of the committee members can be found at: www.usc.edu/compliance. The Vice

Provost for Research, or his or her designee, shall chair the Disclosure Review Committee. At the request of the dean of a school, the Provost's office may, at its discretion, appoint a school specific Disclosure Review Subcommittee, which may include members or non-members of the University-level Disclosure Review Committee. The Disclosure Review Committee will oversee the Subcommittee's activities and will set deadlines for the Subcommittee to report back with its findings.

5.7 The Vice Provost for Research or his or her designee, shall present the "Statement of Outside Interest Related to Research" to the members of the Disclosure Review Committee or Subcommittee for their consideration to determine whether a conflict of interest exists and, if so, to recommend to the Vice Provost for Research what conditions or restrictions should be imposed by the University to manage, reduce or eliminate such conflicts. The Vice Provost for Research may refer a Subcommittee recommendation to the University-level Disclosure Review Committee.

5.8 The Health Sciences Campus Institutional Review Board also has an important and legitimate role to play in determining if a conflict of interest in research exists regarding clinical research, and in determining if a proposed remedy is sufficient to protect research integrity and human participants. Accordingly, the Disclosure Review Committee may seek input and recommendations from the Institutional Review Board Chairperson or designee when determining how best to manage an actual or apparent conflict relating to research involving human subjects.

5.9 The Disclosure Review Committee or Subcommittee shall meet on a regular basis, as determined by the Vice Provost for Research. The Vice Provost for Research shall educate the members of the Disclosure Review Committee about the importance of confidentiality in its deliberations and will take reasonable steps to ensure the confidentiality of the information provided. Meetings will be closed for confidentiality reasons. However, investigators or other individuals with relevant information may be invited to discuss a particular project, as appropriate. Committee members who breach the confidentiality requirements will be sanctioned as appropriate, including removal from the Disclosure Review Committee.

5.10 Given the complexity of financial relationships within the University, disclosures of actual or apparent conflicts of interest will be handled by the Disclosure Review Committee on a case-by-case basis to determine whether a researcher's financial or personal interests are related to University research and constitute a conflict of interest, and if so, how the conflict should be managed. Many conflicts can be managed, after an appropriate evaluation, in the following manners. Situations will be found to be:

- Permitted as is, because the disclosed personal information does not represent an apparent or actual conflict of interest or other possible source of unreasonable bias or inappropriate activity, or

- Permitted contingent upon the implementation of one or more committee recommendations, to manage an apparent or actual conflict or otherwise preclude unreasonable levels of bias or inappropriate activities, or
- Unacceptable, and thus prohibited.

5.11 Options for management of a conflict and a mechanism for reporting back to the Disclosure Review Committee or Subcommittee should be developed in each case. Possible options include, but are not limited to:

- Public disclosure of all relevant information, including disclosure when submitting proposals, publications and manuscripts, making oral presentations or presenting abstracts, or in the informed consent process when enrolling human subjects in research,
- Providing copies to the Disclosure Review Committee of any financial or other disclosure statements submitted to journal editors, conferences, etc.,
- Reformulation of the research workplan,
- Restrictions on enrolling or obtaining informed consent from human participants,
- Restrictions on the analysis of data,
- Close monitoring of the research project by independent reviewers,
- Divestiture of relevant financial interests,
- Creation of escrow account to hold equity interests or intellectual property interests that create an actual or apparent conflict of interest;
- Restrictions on the transfer or sale of equity or intellectual property interests,
- Termination or reduction of involvement in the relevant research project,
- Termination of inappropriate student involvement in projects,
- Severance of outside relationships that pose conflicts,
- Removal from the research project of an Investigator with an apparent or

actual conflict of interest,

- Monitoring and oversight by the Disclosure Review Committee or Subcommittee or by an individual delegated to monitor by the Disclosure Review Committee. Any such Subcommittee or delegated individual will report to the Disclosure Review Committee.

5.12 In some cases, the Disclosure Review Committee or Subcommittee may consider steps taken to minimize potential bias, and protective factors in the design of the study, such as multiple investigators, blinding, or objective endpoints.

5.13 In cases involving conflicts of commitment, the Disclosure Review Committee or Subcommittee shall seek input from the supervisor, Division Chief, Chair or Dean of the Investigator who has an apparent or actual conflict of commitment. The Investigator's supervisor will be asked to assist the Disclosure Review Committee or Subcommittee in determining whether an actual or apparent conflict of commitment exists. It is expected that the Investigator's supervisor would be in the best position to determine if the Investigator has been devoting the appropriate level of effort to his or her USC responsibilities. The Disclosure Review Committee also can refer a matter to the relevant Dean or Subcommittee for review and management at the school level.

5.14 The Disclosure Review Committee and Subcommittee will make their recommendation to the Vice Provost for Research, who will make the final determination regarding management of the conflict at issue, whether the recommendation is made at the school-specific or University level. The Vice Provost for Research will notify the individual who has the potential or actual conflict in writing of the University's determination. The Vice Provost for Research also will notify the relevant Investigator (if the Investigator is not the individual making the disclosure) and, if appropriate, the relevant Dean. The Vice Provost for Research may notify other individuals on campus, as appropriate, who have a "need to know," (e.g., the HSC IRB Chairperson, the Assistant Dean for Research or equivalent at the relevant school). All decisions must be documented.

5.15 In the event that a possible or apparent conflict of interest is identified in connection with PHS or NSF funded awards, the Vice Provost for Research, or his or her designee, will report to the federal awarding agency the existence of a financial conflict of interest and assure that the conflict has been managed, reduced, or eliminated. Furthermore, if for any reason the conflict of interest cannot be managed satisfactorily, then the federal funding agency will be informed promptly.

5.16 Violations that appear to have resulted in a misrepresentation of research results will be handled according to the University's policies for dealing with allegations of misconduct in research, and other misconduct will be handled under the procedures

specified in the Faculty Handbook. Violations of federal or state statutes and guidelines must be handled according to federal and state laws and requirements.

5.17 A faculty member seeking review of the decision by the Vice Provost for Research may do so by filing a grievance under the provisions of the Faculty Handbook on any of the grounds on which a tenure decision may be grieved. The decision of the Vice Provost for Research will remain in full force and effect throughout the review process.

5.18 Records relating to actual conflicts of interest and the determinations of the Disclosure Review Committee will be kept by the Vice Provost for Research until three years after the termination or completion of the project, whichever is later. The Vice Provost for Research will take reasonable steps to protect the confidentiality of the information as well as the recommendations for managing the actual or potential conflict. At the discretion of the Vice Provost for Research, a Subcommittee may maintain certain records, as necessary, to assist the Subcommittee in managing an actual or perceived conflict, provided the Subcommittee has established appropriate safeguards to maintain confidentiality of the records.

5.19 This policy does not preclude a Dean from requiring Investigators in his or her school to provide additional conflict of interest information or to do so on a more regular basis (e.g., annually).

5.20 Faculty, staff and students will receive guidance in interpreting this policy and education regarding situations to avoid that could lead to conflicts of interest and whom to consult when questions arise.

6.0 **Disclosure Review Committee Charges**

When presented with the facts of a given situation, the Disclosure Review Committee must first determine if there is legitimate cause for concern over inappropriate behavior or the injection of undue bias into the professional activities of an Investigator or his or her staff. In order to make this determination, the Committee should inquire into the following:

- Has all relevant information concerning the individual's activities been acquired (i.e., has there been full disclosure)?
- If the research at issue is a clinical trial, in what phase is the clinical trial? What kind of intervention is involved (therapeutic or non-therapeutic)?
- If equity interests are involved, is the equity held in a privately held or publicly traded company? What is the size of the company?

- Is the financial relationship with the entity fixed (e.g., fixed payment) or variable (e.g., equity, stock options)?
- What influence, if any, does the individual have over the entity at issue?
- Do the individual's relevant financial or other interests exceed predetermined thresholds of acceptability, where specified?
- Do the faculty member's reported external commitments exceed permissible levels?
- Is there any indication or perception that research results have not been faithfully and accurately reported?
- Is there any indication or perception that the individual in his or her professional role has improperly favored any outside entity or appears to have incentive to do so?
- Has the individual inappropriately represented the University to outside entities?
- Does the individual appear to be subject to incentives (consulting payments, finders fees, equity interests) that might lead to inappropriate bias?
- Are students or USC employees performing services for a company in which an Investigator or Close Relation of an Investigator has an ownership interest or from which he or she receives any type of remuneration?
- Is there any indication or perception that obligations to the University are not being met?
- Is the individual involved in a situation similar to any of those described earlier in the document that might raise questions of bias, self-dealing, inappropriate use of University assets, poor management, or impropriety?
- Could the individual's circumstances suggest a violation of federal, state, or local laws and requirements?

If as a result of this inquiry, it appears that there may be an apparent or actual conflict of interest, the Disclosure Review Committee must ascertain whether appropriate management of the conflict is in place or could be implemented to address the possible conflicts. In this case, the Disclosure Review Committee will determine, as relevant, the following:

- Will the research workplan receive independent peer review prior to its initiation?

- Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of the institution?
- Are there mechanisms in place to prevent the introduction of bias into research projects (i.e., Is the protocol double-blinded? Are research subjects randomly selected?)?
- Will the project be supervised by someone with authority and no conflicting interests?
- Are there means to verify research results (e.g., independent corroboration in another lab, FDA review)?
- Will data and materials be shared openly with independent researchers? If not, who determines accessibility to such resources?
- Will the product of the collaborative effort with an outside party be published in the peer-reviewed scientific literature?
- Will the sponsorship and relevant interests receive acknowledgment in public presentations of the research results?

As a result of this inquiry, the Disclosure Review Committee or Subcommittee will make a recommendation to the Vice Provost for Research regarding the appropriate manner of addressing any real or apparent conflicts of interest, and will communicate such to the relevant Investigator.

7.0 **Resources**

Objectivity in Research - NIH Guide

<http://grants.nih.gov/grants/guide/notice-files/not95-179.html>

Conflict of Interest Policies – NSF Grant Policy Manual

<http://www.nsf.gov:80/bfa/cpo/gpm95/ch5.htm#ch5-6>

OHRP Draft Interim Guidance - Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators and IRBs to Consider When Dealing with Issues of Financial Interest and Human Subject Protection

<http://ohrp.osophs.dhhs.gov/nhrpac/mtg12-00/finguid.htm>

American Society of Gene Therapy - Policy Position Statement

<http://www.asgt.org/policy/index.html>

AAMC Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research

<http://www.aamc.org/research/dbr/coi.htm>

Food and Drugs: Financial Disclosure by Clinical Investigators

http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr54_01.html

USC Purchasing Policy – Conflict of Interest

http://www.usc.edu/bus-affairs/admin_serv/purchasing/policies.html#conflict

USC Conflict of Interest Policy

<http://www.usc.edu/policies>

AAU Report on Individual and Institutional Financial Conflict of Interest

<http://www.aau.edu>

Harvard University: Policy on Conflicts of Interest and Commitment

<http://www.hms.harvard.edu/integrity/conf.html>