

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

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1.0 **Purpose**

The objective of this policy is to promote the highest ethical standards in situations where conflicts of interest may occur in the conduct of research. This policy is intended to help research investigators (including faculty, staff and students) recognize situations that raise an appearance of conflict and to ensure that such situations are properly reviewed and resolved.

This policy represents one aspect of the university's commitment to address and manage conflicts of interest. As set forth more fully in the Conflict of Interest and Ethics policy, the university also has policies that address conflicts of interest with respect to Employment and Business Practices, Conflict of Commitment and Personal Conflict of Interest. Because multiple types of conflict may arise in the conduct of research, individuals should also review and familiarize themselves with USC's Conflict of Interest and Ethics policy.

In addition, researchers who are also healthcare providers must comply with USC's *Policy Regarding Relationships With Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers*, particularly the sections of the Policy that address consulting and services arrangements, receipt of gifts, and the conduct of research sponsored by pharmaceutical companies, medical device companies, health care suppliers, and their employees or agents.

2.0 **Principles**

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 intellectual property that will help meet societal needs. At the same time, USC faculty, staff, and students must be mindful of conflicts of interest that may arise from these relationships, and affect our commitment to:

- Discharging our obligations to others in a fair and honest manner, as embodied in

- USC's Code of Ethics;
- Educating students;
 - Ensuring academic freedom;
 - Protecting the safety of patients under our care and participants in research;
 - Protecting both the appearance and actual integrity and objectivity of research, instruction, and public service; and
 - Bringing the fruits of research to the benefit of society through the transfer of University-developed knowledge to the public or private sector.

The policy and procedures are separated into three major components that promote these principles:

- **Identification:** To assist university community members in identifying conflicts;
- **Disclosure:** To provide a clear mechanism to disclose the actual or apparent conflict to the appropriate university representative; and
- **Action:** To address actual or apparent conflicts either through appropriate management or through prohibition of the proposed relationship.

3.0 **Scope**

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, clinical trials and also to unfunded research projects.

This policy supersedes the University of Southern California Conflict of Interest in Research: Policy and Procedure, dated November 1, 2002.

4.0 **Definitions**

4.1 **Research**

"**Research**" is a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral and social-sciences research or other scholarly activity.

4.2 **Investigator**

An "**Investigator**" is the principal investigator, co-principal investigator, and co-investigator.

4.3 Research Personnel

“**Research Personnel**” is any other USC employee, whether faculty or staff, who contributes to a research activity, whether or not the research is funded, and regardless of status (e.g., faculty key personnel, research associates, technicians, nurse coordinators, administrators, graduate assistants).

4.4 Close Relation

"**Close Relation**" means the spouse, domestic partner, or dependent child of an Investigator or Research Personnel. In addition, a colleague, sibling, parent, or other relation is considered a Close Relation under this policy when an Investigator and/or Research Personnel knows that the individual maintains a Conflict of Interest that may be impacted by research the Investigator and/or Research Personnel is conducting.

4.5 Conflict of Interest

A "**Conflict of Interest**" is a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research. Conflicts of Interest include non-financial as well as financial conflicts, because non-financial interests can also come into conflict with a researcher's primary commitment to maintain scientific objectivity. Investigators should not only consider situations that are unacceptable, but also gray areas that might create the appearance of a Conflict of Interest.

Conflicts of Interest related to human subjects present unique challenges for researchers and for the University. USC is committed to protecting the safety of all patients under our care and all human subjects participants in research. Therefore, all Conflicts of Interest arising out of human subjects research will be subject to a higher level of scrutiny.

Although not an all-inclusive list, each of the following is a type of Conflict of Interest maintained by either an Investigator, Research Personnel or the Close Relation of either that must be disclosed in accordance with this policy:

Financial Interests

- Maintaining a **private equity interest** (e.g., stocks, stock options or other ownership interests not publicly traded) in a research sponsor or licensee, or in a company having an economic interest in the research, regardless of the value of such equity interest. (See Section 4.6, “Significant Conflict”).

- Maintaining a **publicly traded equity interest** of \$10,000 or more (except when the ownership interest is managed by a third party such as a mutual fund) or .5% of the valuation of a research sponsor or licensee, or in a company having an economic interest in the research. (See Section 4.6, “Significant Conflict”).

Management Roles

- Holding a **management role** (e.g., director, officer, scientific, or technical appointment where the Investigator or Research Personnel has significant decision-making authority) in a research sponsor, licensee, or in a company having an economic interest in the research; or any other instance where the Investigator or Research Personnel has significant decision-making authority within the outside entity. (See Section 4.6, “Significant Conflict”).

Students

- Using a student to perform services for a company in which the Investigator, Research Personnel, or the Close Relation of either, has an ownership or management role when (1) the student is currently enrolled in an Investigator, Research Personnel, or the Close Relation of either’s class; or (2) the Investigator, Research Personnel, or Close Relation of either currently supervise(s) the student in an academic capacity; or (3) the Investigator, Research Personnel, or the Close Relation of either otherwise has the ability to influence the academic progress of the student.

Funding and Compensation

- Maintaining a **financial interest** or **management role** (see above) in a research sponsor of the Investigator and/or Research Personnel’s laboratory.
- Maintaining a **financial interest** or **management role** (see above) in a company who has given, or expressed interest in giving, a major gift to the Investigator and/or Research Personnel’s department or school.
- Receiving any **incentive payments**, bonus payments or finders fees relating to the proposal, conduct or reporting of research, regardless of the amount of compensation or payments received (e.g., additional payments by research sponsors to Investigators or Research Personnel who enroll a certain number of participants in a project within a certain period of time). (See Section 4.7, “Prohibited Conflict”).

- Accepting **personal payments for services from any sponsor, or any organization or individual having an economic interest in the investigator's research, that total \$10,000 or more** when aggregated in any twelve month period. These payments include: consulting arrangements, non-managerial scientific or technical appointments, and payments for lectures and similar public appearances, but exclude reasonable reimbursement of expenses associated with travel and provision of services.¹
- Accepting **gifts, gratuities or special favors** from an actual or prospective sponsor of an Investigator's research, other than occasional gifts of nominal or modest value (less than \$50 in value or isolated invitations to meals). (See Section 4.7, "Prohibited Conflict").²

Intellectual Property³

- Maintaining a financial interest or management role (see above) in a company that is **negotiating a license** to intellectual property from USC.
- Receipt of **intellectual property rights** (e.g., patents, copyrights or royalties from such rights) from a research sponsor by an Investigator, Research Personnel or the Close Relation of either.
- An agreement that **restricts an Investigator or Research Personnel's public reporting** of the information developed by an Investigator or Research Personnel under the agreement, or the existence of the agreement, *in combination with receiving any form of outside compensation from the sponsor, or in combination with holding an officer position or private equity with the sponsor.*

¹ Investigators and/or Research Personnel who are healthcare providers are subject to additional requirements when engaging in professional or consultative services on behalf of pharmaceutical suppliers and device manufacturers. For more detail, please review USC's *Policy Regarding Relationships With Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers*.

² Investigators and/or Research Personnel who are healthcare providers are subject to additional requirements when accepting gifts, gratuities, or special favors from pharmaceutical companies, medical device companies, health care suppliers, and their employees or agents. For more detail, please review USC's *Policy Regarding Relationships With Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers*.

³ For a complete explanation of the rights and responsibilities of USC faculty, staff, and students with respect to Intellectual Property, please see USC's *Intellectual Property Policy* at www.usc.edu/policies.

4.6 Significant Conflict

A “**Significant Conflict**” is a Conflict of Interest that is presumed to be unacceptable unless the Investigator or Research Personnel is able to present compelling circumstances that justify allowing the research to proceed despite the presence of the Significant Conflict. Significant Conflicts include, but are not limited to:

- Any Conflict of Interest on research involving **human subjects** that involves a financial interest, management role, or payments for personal services that total \$10,000 or more when aggregated in any twelve month period.
- Using a student to perform services for a company in which the Investigator, Research Personnel, or the Close Relation of either, has an ownership or management role when (1) the student is currently enrolled in an Investigator, Research Personnel, or the Close Relation of either’s class; or (2) the Investigator, Research Personnel, or Close Relation of either currently supervises the student in an academic capacity; or (3) the Investigator, Research Personnel, or the Close Relation of either otherwise has the ability to influence the academic progress of the student.
- Any sponsored research agreement with an outside entity in which the Investigator, Research Personnel or the Close Relation of either:
 - Holds any **private equity interest** (e.g., stocks, stock options, or other ownership interests);
 - Holds a **publicly traded equity interest in excess of \$50,000** in a research sponsor or licensee (except when the equity interest is managed by a third party such as a mutual fund), or in a company having an economic interest in the research;
 - Holds a **management role** in a research sponsor or licensee (e.g., a director, officer, or other position that has significant decision-making authority).

4.7 Prohibited Conflict

A “**Prohibited Conflict**” is a Conflict of Interest that is never acceptable. Prohibited Conflicts include, but are not limited to:

- **Transfer of intellectual property rights** arising out of research conducted at USC to an outside entity, regardless of whether the outside entity is a research sponsor or the Investigator maintains any Conflict of Interest with the outside entity, without the express written consent of the University.
- Any **incentive payments, bonus payments, finders fees, or any type of payment or incentive based on outcome** relating to the proposal, conduct, supervision, or reporting of research, or with respect to the evaluation of a product or service intended for a commercial market (e.g., a clinical trial for a pharmaceutical company), regardless of the amount of compensation or payments received.
- Any sponsored agreement in which **publication rights are restricted** for proprietary or other reasons, in combination with the Investigator or Close Relation receiving any form of payment, holding any private equity interest, or holding publicly-traded equity interests of \$10,000 or more (except when the equity interest is managed by a third party such as a mutual fund) or .5% of the outside entity’s valuation, or holding a management role;
- **Accepting gifts, gratuities or special favors from an actual or prospective sponsor of an Investigator’s research, other than occasional gifts of nominal or modest value (less than \$50 in value or isolated invitations to meals).**⁴

4.8 Conflict of Commitment

A “**Conflict of Commitment**” is a conflict between outside activities and a full-time employee’s responsibility to devote his or her primary professional loyalty, time and energy to his or her teaching, research, service, administrative, and clinical duties, as applicable. For example, a full-time faculty member who holds a substantially full-time concurrent position elsewhere has a conflict of commitment. Refer to USC’s *Conflict of Interest and Ethics* policy and the Faculty Handbook for more detail.

⁴ Investigators and/or Research Personnel who are healthcare providers are subject to additional requirements under USC’s *Policy Regarding Relationships With Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers*. (See also Footnote 1, *supra*).

4.9 Conflict of Interest Review Committee (CIRC)

The CIRC consists of faculty members appointed by the Provost's office, a representative from the Office of Compliance, a representative from USC Stevens, a representative from the Institutional Review Board (IRB) or the Office for Protection of Research Subjects (OPRS), an attorney from the Office of General Counsel (non-voting), and representation from the Department of Contracts and Grants (*ex officio* non-voting). The CIRC is charged with reviewing Conflict of Interest disclosures and formulating recommendations to manage, reduce, or eliminate Conflicts of Interest. The Vice Provost for Research Advancement, or his or her designee, shall chair the CIRC.

5.0 **Policy**

Investigators are not permitted to commence any research activity when there is an actual or apparent Conflict of Interest before they receive a written determination from the Vice Provost for Research Advancement as to how to manage the Conflict.

5.1 Identification

5.1.1 Each Investigator and Research Personnel is responsible for determining whether he or she, or his or her Close Relation, has a potential Conflict of Interest or Commitment. Investigators and/or Research Personnel should evaluate potential conflicts of interest not only at the outset of their research, but also when a change occurs in their relationship with an outside entity. This may occur at the time a new proposal is submitted, when a new relationship is established with an outside entity, or when a prior relationship with an outside entity changes.

5.1.2 Investigators and Research Personnel are encouraged to utilize resources within the university community available to assist in identifying and avoiding possible conflicts. These include the Office of Compliance, the Vice Provost for Research Advancement, and the Dean or Associate Dean for Research in the school of the Investigator's primary appointment.

5.1.3 Each Investigator also is responsible for confirming that Research Personnel under his or her supervision who are involved in proposing, conducting or reporting research on the Investigator's project identify and disclose any potential Conflict of Interest, and comply with any measures put in place to manage the Conflict.

5.1.4 If Public Health Service (PHS)-funded research is conducted through subgrantees, contractors, or collaborators, reasonable steps must be taken by USC to ensure that such entities comply with this policy or provide assurances that they have their own conflict of interest policies that comply with PHS regulations.

5.1.5 Investigators and Research Personnel are strongly discouraged from proposing activities when they maintain a Significant Conflict and should never propose activities where they maintain a Prohibited Conflict.

5.1.6 Investigators and Research Personnel who are healthcare providers must also comply with USC's *Policy Regarding Relationships With Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers*, particularly the sections of the Policy that address consulting and services arrangements, receipt of gifts, and the conduct of research sponsored by pharmaceutical companies, medical device companies, health care suppliers, and their employees or agents. These obligations may apply even if a disclosure is not required under this policy.

5.2 Disclosure

5.2.1 Investigators and Research Personnel must disclose potential Conflicts of Interest by following the procedures set forth in Section 6.2 of this policy. If there is doubt as to whether to disclose a potential Conflict of Interest, consult the Office of Compliance.

5.2.2 Conflicts of Commitment must also be disclosed, following the procedures in the *Conflicts of Interest and Ethics* policy. When an Investigator and/or Research Personnel disclose a Conflict of Commitment under the *Conflict of Interest and Ethics* policy, the Investigator and/or Research Personnel must provide a copy of any such disclosure to the CIRC, as well as a copy of all documentation reflecting any management decision. If the Investigator and/or Research Personnel's Chair, Dean, or supervisor, as appropriate, requires subsequent disclosures at specified intervals with respect to a Conflict of Commitment, copies of any such disclosures as well as any documentation reflecting management decisions must also be provided to the CIRC.

5.3 Action

5.3.1 Given the complexity of financial and non-financial relationships within the University, disclosures will be evaluated on a case-by-case basis to determine whether the disclosure constitutes a Conflict of Interest and, if so, to determine an appropriate action.

5.3.2 Many Conflicts of Interest can be managed, reduced, or eliminated after an appropriate evaluation. There are three possible outcomes of the review process:

- Permitted as is;
- Permitted contingent upon the implementation of one or more actions for managing the Conflict of Interest;
- Unacceptable, and thus prohibited.

5.3.3 If a disclosure qualifies as a **Significant Conflict**, the Investigator and/or Research Personnel must present compelling circumstances that justify allowing the research to proceed despite the presence of the conflict. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, the degree to which the interest may be affected by the research, and the degree to which the conflict can be effectively managed.

5.3.4 It is the responsibility of the Investigator and/or Research Personnel to comply with each element of a required management plan. This includes any requirement that the Investigator and/or Research Personnel provide a **follow-up disclosure** at a reasonable time interval after his or her initial disclosure (but no less frequently than once per year) that updates the CIRC and the Vice Provost for Research Advancement on the status of the Conflict of Interest and Investigator and/or Research Personnel's compliance with the measures put in place to manage it.

5.3.5 This policy does not preclude the Provost or a Dean from requiring faculty or staff in his or her school(s) to provide additional Conflict of Interest information or to do so on a more regular basis (e.g., annually).

5.4 Management Plans

5.4.1 Minimum Elements of All Management Plans:

All management plans shall contain, at a minimum, these elements:

- All relevant **publications, proposals and presentations** must contain a statement disclosing support received from, or financial interests in, any source outside of USC;

- All **informed consent documents** in the context of human subjects research must disclose support received from, or financial interests in, any source outside of USC. Conflicted Investigators and/or Research Personnel are not permitted to consent human subjects;
- The Investigator and/or Research Personnel and their Close Relations will not participate in any **intellectual property negotiations**, or other contractual negotiations, between USC and the outside entity;
- Investigators must **notify students** of the presence of a Conflict of Interest if the student is to perform as a research assistant on the research, along with a notification to the student and his or her advisor of the student's rights, and the appointment of a third party faculty member as a monitor of the situation.

The CIRC may also consider steps taken by the Investigator and/or Research Personnel to minimize potential bias and include protective factors in the design of the study, such as using multiple Investigators, blinding, or establishing objective endpoints. Possible management recommendations may apply to the monitoring of research, conduct of research, or the individual's outside interests.

5.4.2 Potential Monitoring Recommendations:

Management plans may contain the following types of management recommendations, which include, but are not limited to:

- Providing copies to the CIRC of any financial or other disclosure statements submitted to journal editors, conferences, etc.;
- Monitoring and oversight by the CIRC or by an individual delegated to monitor by the CIRC;
- Referral to a dean, supervisor or CIRC appointed subcommittee for oversight.

5.4.3 Potential Research Recommendations:

Management plans may also contain the following types of research recommendations, which include, but are not limited to:

- Reformulation of the research workplan;
- Restrictions on the analysis of data;
- Close monitoring of the research project by independent reviewers;
- Termination or reduction of involvement in the relevant research project;
- Termination of inappropriate student involvement in projects;
- Where the Investigator and/or Research personnel are healthcare providers, compliance with USC's *Policy Regarding Relationships With Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers*, as applicable;
- Where the Investigator and/or Research Personnel receive payments for personal services related to research involving human subjects (e.g., consulting arrangements, non-managerial scientific or technical appointments, and payments for lectures and similar public appearances), the IRB may require written disclosure of such payments during the informed consent process, regardless of dollar amount. The IRB may also refer the matter to the CIRC for its consideration, as appropriate.
- Removal from the research project of an Investigator and/or Research Personnel with an apparent or actual Conflict of Interest.

5.4.4 Potential Outside Interest Recommendations:

Management plans may also contain the following types of outside interest recommendations:

- Divestiture of relevant financial interests;
- Creation of an 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;
- Severance of outside relationships that pose a Conflict of Interest.

5.5 Violations and Sanctions

5.5.1 Failure to report a Conflict of Interest, or refusal to cooperate in the management of a Conflict of Interest, may be cause for disciplinary action. Possible violations of this policy include, but are not limited to, failure to file the disclosure form or furnishing false, misleading, or incomplete information on the disclosure form. Sanctions for violations of this policy for faculty will observe all provisions of the policies published in the Faculty Handbook. Sanctions for violations of this policy for students will observe all provisions of the policies contained in SCampus.

Sanctions for violations of this policy for staff or other non-faculty employees will be prescribed by the Associate Senior Vice President for Administrative Operations, and may include termination. The Associate Senior Vice President will notify both the department and the non-faculty employee of the prescribed action. Departments are required to implement the remedial or disciplinary action prescribed by the Associate Senior Vice President of Administrative Operations. A non-faculty employee may file a written appeal with the Senior Vice President for Finance within ten business days of his or her receipt of notice of the disciplinary action. The Senior Vice President for Finance must respond to the employee's appeal within twenty (20) business days.

Any disciplinary action against a faculty member or a non-faculty employee under this policy must take into account the scale of the offense, the individual's intent, and the degree of wrongdoing.

5.5.2 Violations that appear to have resulted from a misrepresentation of research results will be handled according to the University's *Scientific Misconduct Policy*, and other misconduct will be handled under the procedures specified in the Faculty Handbook, and for non-faculty employees as described in section 5.5.1 above, and/or SCampus. Violations of federal or state statutes and guidelines must be handled according to federal and state laws and requirements.

6.0 Procedure

6.1 Identification

6.1.1 Prior to submitting a research proposal for funding, Investigators **must certify on the Proposal Approval Record (PAR)** form that they have read and understand this policy, and that they will comply with any management conditions or restrictions imposed by USC. Investigators must also declare whether the proposal presents any potential Conflict of Interest for the Investigator or Research Personnel.

6.1.2 Any potential Conflict of Interest must also be identified in the body of any research proposal submitted to a sponsoring agency.

6.2 Disclosure

Disclosure is required for all potential Conflicts of Interest, as follows:

6.2.1 An Investigator and/or Research Personnel who has identified a potential Conflict of Interest must disclose it to the Office of Compliance by **submitting a "Statement of Outside Interests Related to Research"** (<http://ooc.usc.edu/ResearchCompliance/ConflictOfInterest.cfm>), whether or not the conflict is related to funded research. When applying for funded research, Investigators are strongly encouraged to submit this statement prior to, or soon after, submitting their proposal.⁵

6.2.2 An updated "*Statement of Outside Interests Related to Research*" must be submitted for any new or previously undisclosed Conflict of Interest, particularly when there is a change in personal, financial or fiduciary status.

6.2.3 Submissions of the "*Statement of Outside Interests Related to Research*" may be provided in a sealed envelope marked "Confidential."

6.2.4 Submissions of the "*Statement of Outside Interests Related to Research*" may also be submitted electronically.

6.2.4 **Research involving human subjects must also be disclosed to the Institutional Review Board (IRB)** on the initial and continuing review application and on the Health Research Association form for non-government funded projects.

⁵ The Vice Provost for Research Advancement and the Office of Compliance will take appropriate steps to protect the confidentiality of the information as well as the recommendations for managing the actual or potential conflict. However, the Vice Provost for Research Advancement will make certain conflict information available, when mandated by sponsoring agencies.

6.3 Action

6.3.1 All disclosed conflicts of interest first receive an administrative pre-review to assess the circumstances of the potential conflict and to formulate potential management plans. When requested, Investigators and/or Research Personnel are required to provide additional information, to perform this initial assessment.

6.3.2 The disclosure and pre-review will be forwarded to the CIRC, which is charged with reviewing all disclosures and formulating recommendations to manage, reduce, or eliminate conflicts of interest, as appropriate. The CIRC shall meet on a regular basis, as determined by the Vice Provost for Research Advancement.⁶

6.3.3 The CIRC will make their recommendation to the Vice Provost for Research Advancement, who will make the final determination, which can fall into any of the following categories: (1) Permitted as is; (2) Permitted contingent upon implementation of a management plan; or (3) Unacceptable, and thus prohibited.

6.3.4 In situations where the CIRC believes that the Investigator and/or Research Personnel has successfully presented compelling circumstances justifying allowing research to proceed despite the presence of a Significant Conflict, it will prepare a summary report describing the nature and amount of the financial interest, as well as the compelling circumstances that justify the rebuttal of the presumption that an unmanageable Conflict of Interest exists. If the Conflict of Interest relates to human subjects research, the report shall be made available to the relevant USC IRB. If the Conflict of Interest relates to a sponsored research agreement with an outside entity in which the Investigator and/or Research Personnel or their Close Relation holds a substantial interest, the report shall be made available to the Dean of the school of the Investigator's primary appointment.

⁶ The Vice Provost for Research Advancement, or his or her designee, shall educate the members of the CIRC 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. Committee members who breach the confidentiality requirements will be sanctioned as appropriate, including removal from the CIRC.

6.3.5 In cases where the CIRC's review of a disclosure raises a potential **Conflict of Commitment**, the CIRC will notify the Investigator and/or Research Personnel's supervisor, Division Chief, Chair or Dean pursuant to the *Conflict of Interest and Ethics* policy, as appropriate. The Investigator and/or Research Personnel's supervisor, Division Chief, Chair or Dean should provide a copy of all documentation reflecting his or her decision with respect to the conflict of commitment to the Vice Provost for Research Advancement.

6.3.6 Once the Vice Provost for Research Advancement makes his or her final determination, he or she will notify the following individuals and/or entities in writing, as appropriate:

- The individual(s) who has the potential or actual Conflict of Interest. If this individual(s) is someone other than the Investigator, the Investigator will be notified as well;
- The relevant Dean;
- If the Conflict of Interest involves human subjects, the Chair of the relevant IRB;
- If the Conflict of Interest has been identified in connection with research conducted at Health Research Association (HRA), the Vice Provost for Research Advancement will notify the Chief Executive Officer of HRA of his or her determination;
- Other individuals on campus who have a "need to know" (e.g., the Associate Dean for Research or equivalent at the relevant school).

6.4 Government Reporting and Appeals

6.4.1 A faculty member seeking review of the decision by the Vice Provost for Research Advancement 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 Advancement will remain in full force and effect throughout the review process.

6.4.2 When a Conflict of Interest has been identified in connection with PHS funded awards, the Vice Provost for Research Advancement, or his or her designee, will report to the federal awarding agency the existence of the conflict and assure that the conflict has been managed, reduced, or eliminated prior to the expenditure of any funds under the award. When a conflict is identified after a project is begun, the Vice Provost for Research Advancement, or designee, will report to the federal awarding agency within sixty (60) days of it being identified.

6.4.3 With respect to research funded by the NSF, if for any reason the Conflict of Interest cannot be managed satisfactorily, then the Vice

Provost for Research Advancement, or his or her designee, will promptly inform the NSF of this fact.

6.4.4 Records relating to disclosures of actual or apparent Conflicts of Interest and the determinations of the Disclosure Review Committee will be kept by the Vice Provost for Research Advancement for three years after the termination or completion of the project, whichever is later.

7.0 **Resources**

Objectivity in Research - NIH Guidance

<http://grants2.nih.gov/grants/policy/coi/index.htm>

Conflict of Interest Policies – NSF Grant Policy Manual

http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

OHRP Guidance on Financial Relationships and Interests in Research Involving Human Subjects

<http://www.hhs.gov/ohrp/humansubjects/finreltn/finalguid.pdf>

AAMC Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research

<http://www.aamc.org/research/coi/firstreport.pdf>

AAU Report on Individual and Institutional Financial Conflict of Interest

<http://www.aau.edu>

Food and Drugs: FDA Guidance on Financial Disclosure by Clinical Investigators

<http://www.fda.gov/oc/guidance/financialdis.html>

USC Purchasing Policy – Conflict of Interest

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

USC Conflict of Interest and Ethics Policy

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

USC Faculty Handbook

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