CONFLICT OF INTEREST IN RESEARCH

1.0 Purpose

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

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 many times produce knowledge and technology that will help to meet societal needs.

In certain circumstances, relationships with outside interests can create, or appear to create, conflicts of interest. While having a conflict of interest does not imply wrongdoing or inappropriate activity, conflicts 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 conflicts be disclosed promptly and thoroughly in the manner provided in this policy. This policy explains the process for identifying and disclosing conflicts and the methods by which they are managed by the university.

Under this policy, there are three categories of conflicts:

- Section 3.7 of this policy identifies conflicts that need to be disclosed. As described in Section 6.2 of this policy, some of these conflicts may be resolved via an expedited administrative review by requiring public disclosure in publications, presentations, and proposals.
- Section 3.9 of this policy describes significant conflicts, which are only permissible if the investigator can demonstrate compelling circumstances to justify continued participation in the research notwithstanding the conflict.
- Section 3.8 of this policy describes prohibited conflicts, which are impermissible in all circumstances, and should not be undertaken.

This policy represents one aspect of the university’s commitment to address and manage conflicts of interest. The university’s Conflict of Interest in Professional and Business Practices policy addresses conflicts relating to business practices, personal conflicts and conflicts of commitment. In addition, employees who are healthcare practitioners must comply with USC’s Relationships with Industry policy, 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 **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, gift funded projects, clinical trials and also to unfunded research projects.

Investigators are not permitted to begin any research activity when there is an actual or apparent conflict of interest before they receive a written determination from the Vice President of Research as to how to manage the conflict. Investigators are not permitted to begin an external activity that would create a conflict of interest relative to ongoing research activity before they receive a written determination from the Vice President of Research as to how to manage the conflict.

3.0 **Definitions**

3.1 **Research**

A systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral and social-sciences research or other scholarly activity.

3.2 **Investigator**

The principal investigator, co-principal investigator, contact principal investigator, or co-investigator. Other persons may be an investigator, but only if they have independent responsibility for some aspect of the design, conduct, or reporting of research.

3.3 **Research Personnel**

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 status (e.g., research associates, technicians, nurse coordinators, administrators, graduate assistants).
3.4 Close Relation

Spouse, domestic partner, or dependent child of an investigator or research personnel.

3.5 Institutional Responsibilities

An investigator’s professional responsibilities on behalf of the institution including, but not limited to, activities such as research, teaching, professional or clinical practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRBs) or Data Safety and Monitoring Boards.

3.6 Conflict of Commitment

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. Refer to USC’s Conflict of Interest in Professional and Business Practices policy and the Faculty Handbook for more detail.

3.7 Conflict of Interest

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 set forth in this policy, but also gray areas that might create the appearance of a conflict of interest.

Conflicts of interest include the following types of interests maintained by an investigator, research personnel or his or her close relations. These must be disclosed under this policy:

Equity Interests

- A private equity interest (e.g., stocks, stock options or other ownership interests not publicly traded) in a research sponsor, or in a company having an economic interest in the research (e.g., licensee), regardless of the value of such equity interest. (See Section 3.9 “Significant Conflict”).

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• A publicly traded equity interest of $5000 or more (except when the ownership interest is maintained in an investment vehicle, such as mutual funds and retirement accounts where the investigator, research personnel or close relation does not directly control the investment decisions made) in a research sponsor or in a company having an economic interest in the research (e.g., licensee). (See Section 3.9, “Significant Conflict”).

Management Roles

• A management role (e.g., director, officer, or similar position of significant decision-making authority) in a research sponsor or in a company having an economic interest in the research (e.g., licensee). (See Section 3.9, “Significant Conflict”).

Funding and Compensation

• Payments for services (other than for conducting the research) from a sponsor funding the investigator or close relation’s research, or any organization or individual having an economic interest in the investigator's or close relation’s research (e.g., licensee), that total $5000 or more when aggregated over a 12-month period. These payments include:
  o consulting arrangements
  o payments for service on a board, advisory committee or review panel, including scientific or technical appointments, except as stated below
  o payments for lectures and similar public appearances
  o honoraria
  o paid authorship

Sponsored travel or reimbursement of expenses associated with travel and provision of services may also be a conflict of interest to the extent the sponsorship/reimbursement is not reasonable. Therefore, all sponsored or reimbursed travel must be disclosed, except as stated below. (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 companies, medical device companies, and their employees or agents. See USC’s Relationships with Industry policy.)

Payments and travel reimbursement from seminars, lectures, teaching arrangements, or service on advisory committees or review panels are

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excluded if they are from:

- a federal, state, or local government agency;
- another university or research institute affiliated with another university; or
- an academic medical center or teaching hospital.

**Intellectual Property**

- Personal receipt of intellectual property rights (e.g., patents, copyrights or royalties) directly from a research sponsor or a company having an economic interest in the research (e.g., licensee).

### 3.8 Prohibited Conflict

A conflict of interest that is never acceptable because there is no feasible way to manage the conflict. These conflicts call into question the integrity of the research and create significant reputational risk for both the researcher and the university. Prohibited conflicts include:

- Participating in a paid “speakers bureau” (i.e., contractual relationships to give talks in which the topic(s) and/or content are provided by the company) for any company that has sponsored the investigator’s research, or that of their close relations.

- Any personal incentive payments, bonus payments, finder fees, or any type of payment or incentive based on outcome that are made directly to the researcher relating to the proposal, conduct, supervision, or reporting of research (e.g., additional personal 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), 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, except for reasonable delays in order to protect proprietary rights (i.e. patent rights), in combination with the investigator, research personnel or close relation holding a conflict of interest.

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1 For a complete explanation of the rights and responsibilities of USC faculty, staff, and students with respect to intellectual property, see USC’s Intellectual Property policy.
• Accepting personal 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). (Investigators and/or research personnel who are healthcare providers are subject to additional requirements under USC's Relationships with Industry policy.)

3.9 Significant Conflict

One whose potential for actual or perceived bias is great enough that the investigator or research personnel must present compelling circumstances as to why the research should proceed despite the presence of the conflict. A significant conflict includes situations when a principal investigator and/or his or her close relation maintains any of the following interests:

• Private equity interests (e.g., stocks, stock options, or other ownership interests) in a research sponsor, unless the investigator provides verification that the equity interest is less than 10% of the outstanding stock of the research sponsor.

• Publicly traded equity interests in excess of $50,000 in a research sponsor (except when the interest is maintained in an investment vehicle, such as mutual funds and retirement accounts, where the investigator does not directly control the investment decisions made).

• Management roles in a research sponsor (e.g., a director, officer, or other position that has significant decision-making authority).

• Receipt of payment for services related to promoting, marketing or selling products (e.g., paid public appearances, endorsements or speaking engagements aimed to encourage purchase or use of products) on behalf of a company for whom the investigator has also conducted (or intends to conduct) university research as an independent evaluator of the company's products.

In the case of human subject research, a conflict is also a significant conflict when any investigator, research personnel and/or his or her close relation maintain any of the following interests:

• Receipt of personal funding and compensation that totals $25,000 or more when aggregated in any 12-month period, from a sponsor or a company that holds an economic interest (e.g., licensee) in the outcome of a human subject trial.
• **Private equity interests** (e.g., stocks, stock options, or other ownership interests) from a sponsor or a company that holds an economic interest (e.g., licensee) in the outcome of a human subject trial regardless of the value of such equity interest.

• **Publicly traded equity interests in excess of $50,000** from a sponsor or a company that holds an economic interest (e.g., licensee) in the outcome of a human subject trial (except when the interest is maintained in an investment vehicle, such as mutual funds and retirement accounts, where the investigator does not directly control the investment decisions made).

• **Management roles** (e.g., a director, officer, or other position that has significant decision-making authority) in a sponsor or a company that holds an economic interest in the outcome of a human subject trial (e.g., licensee).

Significant conflicts will be reviewed in accordance with Section 6.5 of this policy.

3.10 **Student Conflict of Interest**

Exists when a company in which an investigator, research personnel or close relation has an ownership interest or management role retains a student to provide services (paid or unpaid) and:

1. The student is currently enrolled in an investigator’s, research personnel or close relation’s class;
2. The investigator, research personnel or close relation currently supervises the student in an academic capacity;
3. The investigator, research personnel or close relation has the ability to influence the academic progress of the student; or
4. The investigator, research personnel or close relation otherwise supervises the student as a research assistant or student employee.

3.11 **Conflict of Interest Review Committee (CIRC)**

The CIRC, chaired by the Vice President of Research or his or her designee, is charged with reviewing conflict of interest disclosures and formulating recommendations to manage, reduce, or eliminate conflicts of interest. The CIRC consists of faculty members appointed by the Provost's office, a representative from the Office of Compliance, a representative from the USC Stevens Center for

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Innovation (non-voting), 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), a representative from the Department of Contracts and Grants (non-voting), and such other representatives as may be determined by the CIRC.

4.0 Policy

4.1 Investigators and research personnel are responsible for identifying and disclosing actual or potential conflicts covered by this policy. 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.

4.2 Investigators, research personnel and their close relations are responsible for updating their disclosures whenever there is a change to the information contained in the initial disclosure.

4.3 Investigators must submit an annual disclosure of financial interests related to their institutional responsibilities (regardless of whether the interest creates a conflict of interest in research) when mandated by a research sponsor (e.g., the Department of Health and Human Services [HHS]), in accordance with the schedule established by the university. Investigators who are seeking support from HHS must have a current annual disclosure at the time of proposal submission. Investigators with HHS sponsored funding must update their annual disclosures within 30 days of the time they obtain a financial interest with an entity that was not disclosed at the time of the most recent annual disclosure. All changes to financial interests with entities disclosed in the annual disclosure must be updated at the time of the next annual disclosure.

4.4 Investigators are not permitted to begin any research activity when they have reported an actual or apparent conflict of interest before they receive a written determination from the Vice President of Research as to how to manage the conflict. Investigators also are not permitted to begin an external activity that would create a conflict of interest relative to an ongoing research activity before they receive a written determination from the Vice President of Research as to how to manage the conflict.

4.5 Investigators and research personnel must provide timely and accurate information in response to the CIRC and its designees in order for the CIRC to
make an initial determination regarding the disclosure and/or to monitor their compliance with the CIRC management plan.

4.6 In the case of a significant conflict, the investigator or research personnel must present compelling circumstances as to why the research should proceed despite the conflict. This determination 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, and the degree to which the interest may be affected by the research.

4.7 Investigators and research personnel must comply with all of the elements of the CIRC’s management plan, as approved by the Vice President of Research.

4.8 All investigators must complete training relating to conflicts of interest in research as prescribed by the university.

4.9 Each investigator 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.

4.10 Prohibited conflicts are never acceptable and, therefore, should not occur. Immediate action must be undertaken to eliminate any prohibited conflict.

5.0 Procedure to Disclose Conflicts

5.1 Investigators and Research Personnel must disclose potential or actual conflicts of interest:

- At the time of proposal submission.

- In connection with human subjects research, at the time of submission of the initial and continuing review application to the Institutional Review Board (IRB).

- In connection with animal research, at the time of submission of the initial and continuing review application to the Institutional Animal Care and Use Committee (IACUC).

- At any point when the Investigator and/or Research Personnel establish a new outside relationship, or change an existing relationship that creates a potential conflict under this policy.
The university will establish procedures by which Investigators and/or Research Personnel must disclose potential or actual conflicts. The disclosure will require the Investigator and/or Research Personnel to describe the research, the nature of the potential conflict, and to propose how the conflict should be managed, reduced, or eliminated.

5.2 Research sponsors (such as Health and Human Services) may also require that Investigators make an annual disclosure (e.g., prior to a designated date each year) of all outside relationships maintained by them or their Close Relations that relate to the Investigator’s Institutional Responsibilities to USC, regardless of whether the relationship creates a potential conflict of interest. Investigators must adhere to sponsor-specific disclosure requirements.

The university will establish procedures by which Investigators must submit an annual disclosure of all outside interests related to the Investigator’s Institutional Responsibilities. If a potential conflict is first identified through an annual disclosure, the Investigator shall be required to submit a conflict disclosure, as described in Section 5.1.

5.3 Additional disclosures may be needed under other USC policies, as follows:

- Conflicts of commitment must be disclosed following the procedures in the Conflict of Interest in Professional and Business Practices policy. When an Investigator and/or Research Personnel disclose a conflict of commitment under that 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.

- Investigators and Research Personnel who are healthcare providers must also comply with USC’s Relationships with Industry policy and inform their department chair or designee of their outside activities and receive their approval before engaging in the outside activity.

6.0 Managing Conflicts

6.1 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.

6.2 Conflicts of interest generally do not require full CIRC review and may be handled administratively if the conflict is not a significant conflict, does not involve students or human subjects and does not involve payment for personal services in excess of $25,000 in a 12-month period. However, the Vice President of Research, or his or her designee, reserves the right to require CIRC review if appropriate. If a conflict is handled administratively, it will be governed by the General Rule, as described in Section 6.7 of the policy.

6.3 When a disclosure reveals a potential conflict requiring full CIRC review, the pre-review will be forwarded to the CIRC, which is charged with reviewing 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 President of Research. (Information about submission deadlines and CIRC meeting schedules may be found at the Office of Compliance website.)

6.4 The Vice Provost for Undergraduate Programs and the Vice Provost for Graduate Programs, or their respective designees, must approve the portions of a management plan designed to manage an identified student conflict of interest.

6.5 When a disclosure reveals a significant conflict, the CIRC will make an assessment of whether compelling circumstances exist that justify allowing the research to proceed despite the presence of the conflict.

6.6 The CIRC will make a recommendation to the Vice President of Research as to whether a potential conflict is manageable and, if so, the management plan that should be implemented. The Vice President for Research will make the final determination.

6.7 All management plans will contain, at a minimum, the following elements. Collectively, these elements constitute the “General Rule.”

- 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

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subjects;

- The investigator and/or research personnel and their close relations will not represent the university 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. An independent faculty member must also be designated to monitor the student’s progress and protect his or her interests.

6.8 Management plans may contain a variety of additional options for the investigator to pursue, including:

- 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.

- 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 Relationships with Industry policy;

- 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;

- Removal from the research project of an investigator and/or research personnel with an apparent or actual conflict of interest;

- Creation of an escrow account and/or blind trust to hold equity interests or intellectual property interests that create an actual or apparent conflict of interest;

- Divestiture of relevant financial interests;

- Severance of outside relationships that pose a conflict of interest.

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.

6.9 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 in Professional and Business Practices policy, as appropriate. The investigator and/or research personnel’s supervisor, division chief, chair or dean must provide a copy of all documentation reflecting his or her decision with respect to the conflict of commitment to the Vice President of Research.

6.10 Once the Vice President of Research 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 President of Research will notify the Chief Executive Officer of HRA of his or her

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determination;
- Other individuals on campus who have a “need to know” (e.g., the associate dean for research or equivalent at the relevant school).

6.11 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 President of Research 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.

6.12 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). Any school-specific annual disclosure requirement must utilize the system developed by the university for such disclosures, and must be approved by the Office of Compliance and the Provost in consultation with the faculty council of the school.

7.0 Violations and Sanctions

7.1 Failure to report a conflict of interest or to submit a required annual disclosure, 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 a disclosure form; furnishing false, misleading, or incomplete information on a disclosure form; or failure to follow a management plan. The CIRC may recommend suspension of research on the part of any individual who has violated this policy. The Vice President for Research will make the final determination on whether to adopt CIRC recommended sanctions and how to execute the recommended sanctions.

Additional sanctions for violations of this policy will comply with the provisions of the Faculty Handbook, USC policies and SCampus, as applicable.

7.2 In addition, in the case of HHS-funded research, if the investigator fails to disclose or update a conflict in a timely fashion, or to comply with the management plan, the university will review the investigator’s activities and the research project to determine whether any research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research. The university will document the review and notify the sponsor promptly in the event bias is found. The report will include:

- Project number;
- Project title;
- Principal investigator or contact principal investigator if a multiple PI model is used;
- Name of the investigator with the conflict;
- Reason(s) for the retrospective review;
- Methodology used for the retrospective review, and
- Findings and conclusions of the review.

7.3 If actual bias is found, the university will notify the sponsor promptly and submit a mitigation report. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project. It will also outline the university's plan to eliminate or mitigate the effect of the bias.

8.0 Government Reporting and Appeals

8.1 A faculty member seeking review of the decision by the Vice President of Research has a right to a hearing under the grievance provisions of the Faculty Handbook on any of the grounds on which a reappointment or promotion decision may be grieved. The decision of the Vice President of Research will remain in full force and effect throughout the review process.

8.2 When a conflict of interest has been identified in connection with HHS-funded awards, the Vice President of Research, or his or her designee, will notify the sponsor and submit a report in accordance with HHS requirements, documenting the conflict and how it will be managed.

8.3 USC is required to respond to requests for information about conflicts of interest on HHS funded research within five business days of receipt of the request. Requests should be directed to the Vice President for Research or Office of Compliance.

8.4 With respect to research funded by the NSF, if for any reason the conflict of interest cannot be managed satisfactorily, then the Vice President of Research, or his or her designee, will promptly inform the NSF of this fact.

8.5 Records relating to disclosures of actual or apparent conflicts of interest and the determinations of the CIRC will be kept by the Vice President of Research for three years after the termination or completion of the project, whichever is later.

Related Policy and Additional References

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Conflict of Interest in Professional and Business Practices

Relationships with Industry

Faculty Handbook

HHS Final Rule on Conflicts of Interest

Financial Conflict of Interest - NIH Guidance

Conflict of Interest Policies – NSF Grant Policy Manual

AAU/AAMC Guidelines on Managing Conflicts of Interest
http://www.aau.edu/publications/reports.aspx?id=6900

Food and Drugs: FDA Guidance on Financial Disclosure by Clinical Investigators
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm

USC Purchasing Policy – Conflict of Interest
http://fbs.usc.edu/depts/purchasing/page/692/ps-policies-procedures/

Responsible Offices: Office of Research
research.usc.edu
(213) 740-6709

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