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

Date Issued: September 1, 2009

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1.0 Purpose

The objective of this policy is to promote the highest ethical standards in the conduct of research in situations where institutional conflicts of interest (“ICOI”) may occur, and to determine those instances when an ICOI is unacceptable. An ICOI may occur when a financial interest of the University (e.g., investments held by the University in a company) has the potential to bias research conducted by its employees or students, or creates an unacceptable risk to human subjects.

This policy represents one aspect of the University’s commitment to address and manage conflicts of interest. Other University policies that address conflicts of interest include:

- The University’s Conflict of Interest in Research policy addresses conflicts of interest that arise from individual financial interests related to research.
- The University’s Conflict of Interest and Ethics policy addresses individual conflicts of interest with respect to Employment and Business Practices, Conflict of Commitment, and Personal Conflict of Interest, and requires that university employees not allow a personal or outside interest to interfere with their duties and responsibilities to the University.
- The University’s policy on Relationships with Pharmaceutical Suppliers, Biotech and Medical Equipment Manufacturer and Other Healthcare Suppliers addresses consulting and service 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 research and to benefit society through the transfer of University-developed knowledge to the public and private sector. The University’s research will
be conducted with integrity and objectivity, and in a manner that protects the safety of human subjects. As set forth in this Policy, the University is also committed to ensuring that its own financial interests do not create an ICOI that might bias research conducted by its faculty, students and staff.

3.0 Definition

3.1 Research: Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral and social-sciences research or other scholarly activity. A research project may be sponsored by an externally funded grant or contract, a gift to the university, or university funds.

3.2 Human subject: A human subject is a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

3.3 Outside Entity: Any organization (including for-profit or not-for-profit and whether incorporated or otherwise) that is not owned or controlled by the University, or any individual that is not employed or otherwise affiliated with the University.

3.4 Institutional Conflict of Interest: An Institutional Conflict of Interest exists when the financial interests of the University have the potential to cause bias in the conduct of research. Such conflicts occur most frequently in situations where a research project provides a direct benefit to an outside entity through evaluation, validation, trial or test of an invention, product, drug, service or technology, and the University holds a financial interest in the outside entity. For purposes of this policy, a University-held financial interest in an outside entity includes, but is not limited to, receipt of royalties from the outside entity or an ownership interest in the outside entity.

3.5 Significant Institutional Conflict of Interest: An ICOI is deemed a “Significant Conflict” when a research project includes human subjects and any of the following conditions applies:

- The University holds any private equity in the outside entity, or
- The University has the potential to receive cash payments from existing licensing arrangements with the outside entity; or
- The University maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of human subject research as a result of technology licensing activities.
4.0 Policy

All ICOIs that do not present a Significant Institutional Conflict of Interest shall be managed by disclosing the University’s relationship with the outside entity in all relevant publications, proposals, consent documents and presentations. The requirement of such disclosure is limited to those circumstances where the investigator knows or has reason to know of the University’s relationship with the outside entity.

Significant Institutional Conflicts of Interest are presumed to be unacceptable, unless compelling circumstances are present that justify allowing the research to proceed at the University despite the presence of a significant conflict. The University conducts a fact-specific inquiry to determine whether the specific circumstances of a relationship are compelling or not, based on these considerations:

- Nature of the research, current phase of development and intentions for subsequent phases.
- Magnitude of potential risks to human subjects inherent in the research, and how those risks could be affected as a result of the ICOI.
- Degree to which university and its employees stand to benefit financially from the research.
- USC’s financial and/or reputation risk relative to potential benefit of research.
- Likelihood that a societally important development project will be substantially impeded if the research is not performed at USC.
- Societal impact of successful development, relative to potential risk to the university.
- Magnitude of potential risks posed to students engaged in the research project.

The assessment as to whether compelling circumstances exist will be made under the procedures described in Section 5.0.

5.0 Procedure

5.1 Anticipation: At the earliest stage of the technology licensing and development process, the USC Stevens Institute, the Office for the Protection of Research Subjects and the Office of Research Advancement will advise investigators, licensees and equity partners on the ethics and value of avoiding conflicts of interest in evaluating, validating, or testing University-owned intellectual property (as defined by USC’s Intellectual Property policy). Investigators will be encouraged to engage independent organizations, with no conflicts of interest, for these purposes.

5.2 Notification: As soon as any University department, regulatory oversight committee, faculty member, staff employee or student becomes aware of a potential ICOI, he or she must notify the Vice Provost for Research Advancement (VPRA). In particular, the USC Stevens Institute will notify the Vice Provost for Research Advancement in any instance where the University has taken, or intends to take, equity in an outside entity related...
to USC’s intellectual property, or will receive royalty income related to USC’s intellectual property.

5.3 Assessment: The VPRA will make an initial assessment of whether an ICOI exists, and then take the following actions:

- If the VPRA determines that an ICOI exists, but is not a Significant Conflict, the investigator will be instructed by the VPRA on how to disclose the University’s relationship in all publications, proposals, consent documents and presentations.
- If the VPRA determines that the ICOI is a Significant Conflict, the investigator will be given the opportunity to provide a detailed written explanation of compelling circumstances why the research should proceed. When the investigator chooses to offer compelling circumstances, the VPRA will also notify the relevant IRB that assessment will take place about the potential for a Significant ICOI. If the investigator chooses not to provide compelling circumstances, then the research will not be permitted.
- If it is determined that no ICOI exists, the disclosing party will be notified that no action is needed.

5.4 Explaining Compelling Circumstances: If an investigator believes that a research project should be conducted within the University, despite the presence of a Significant ICOI, he or she should provide a detailed written explanation of the compelling circumstances to the Vice Provost for Research Advancement, addressing the criteria in Section 4.0. This explanation must also include the steps taken to secure an alternate research site outside of the University, and the justification for why the alternate research site is inadequate.

5.5 Assessment and Determination: If an investigator submits an explanation of compelling circumstances, the VPRA will appoint a committee of three expert advisors with no financial or other apparent or actual conflict of interest. Excepting Phase 1 trials and low risk studies, the majority of the advisors must be external to the University. These experts will formulate a recommendation as to whether the significant conflict is manageable and, if so, how it should be managed.

The University Conflict of Interest Review Committee (CIRC) will review the recommendations of these experts, which are advisory, and make its own recommendation to the Vice Provost of Research Advancement. Their recommendation should also take into consideration any personal conflicts of interest of individual investigators, which must be separately disclosed under the Conflict of Interest in Research Policy. The CIRC’s recommendations may include:

- Prohibiting the research from taking place at USC,
- Permitting the research to proceed, subject to a plan for managing the ICOI and any personal conflicts of interest,
• Permitting the research to proceed coupled with divestiture of financial interests of the University and individual investigators.

The CIRC will communicate its recommendations, which are advisory, to the Vice Provost for Research Advancement for final determination. The VPRA’s decision will be communicated to the relevant IRB, the Department of Contracts and Grants, USC Stevens, the Dean or Department Chair in the school where the research is taking place, and Health Research Association, as applicable. If the research is permitted to proceed at USC, the decision should document the compelling circumstances, and document the plan used to manage the ICOI. The IRB may elect to implement additional safeguards for the protection of human subjects.

6.0 Recusal

As set forth in the University’s policy on Conflict of Interest and Ethics, any person in a position of authority, including department chair, center or institute director, dean, VPRA or provost, who has a direct financial interest in the outcome of a research project under his or her authority, should recuse him or herself from any decision pertaining to either an institutional or personal conflict of interest in research, or pertaining to any level of oversight over the research project. In case of recusal, a substitute person will be designated by the dean, provost or president to act in place of the recused individual.

7.0 Violations and Sanctions

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, furnishing false, misleading, or incomplete information.

Sanctions for violations of this policy for faculty will be in accordance with all applicable provisions of the policies published in the Faculty Handbook.

Sanctions for violations of this policy for students will be in accordance with all applicable 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 Administration within fifteen (15) calendar days of his or her receipt of notice of the disciplinary action.
Any disciplinary action under this policy will take into account the scale of the offense, the individual’s intent, and the degree of wrongdoing.

Violations that involve a misrepresentation of research results will be handled according to the University’s Scientific Misconduct Policy.

Violations of federal or state statutes and guidelines must be handled according to those requirements.