

**Subject: Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research**

**Background**

The University of California addresses the various aspects of institutional financial conflicts of interests in research through a number of principles, guidelines and policies, but has not promulgated a single, unified institutional conflict of interest in research policy document. In order to provide more easily-accessed information pertaining to *currently existing* systemwide principles, guidelines, and policies pertaining to institutional conflicts of interests in research, the following **Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research** has been issued.

This document does not represent a change in University's principles, guidelines or policies, and is intended rather as a compendium of the University of California's current, existing systemwide principles, guidelines, and policies with regard to institutional conflict of interest in research. Where appropriate, it references relevant state and federal laws in addition to UC guidance, policy and procedures.

## **SUMMARY STATEMENT OF PRINCIPLES AND POLICIES ON INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH**

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### **1. Introduction**

This document sets forth the University of California's principles, policies and measures with regard to institutional conflict of interest in research.

Financial relationships between research universities and private entities that support research have grown increasingly complex. The benefits of these partnerships to the conduct of research and to society at large are significant. They have led to a rapid transformation of university research into marketable products and technologies for the benefit of society, and to the launching of new industries to pursue the development of university inventions. Nevertheless there is concern that such relationships could affect institutional decisions at the cost of research integrity. This policy addresses these concerns and states the principles of academic integrity and openness of inquiry to which the University of California adheres.

The University of California's mission of teaching, research and public service must not be disrupted by the pressures of economic gain. The public's trust in the University of California's integrity and commitment to the pursuit of knowledge must not be undermined by improper influence of institutional commercial partnerships on research decisions.

### **2. Definition of Institutional Conflict of Interest in Research**

An institutional conflict of interest in research may arise when a financial interest of the institution compromises or biases or appears to compromise or bias: 1) the design, conduct, or reporting of the research being funded; or 2) the design, conduct or reporting of other research being or to be conducted by the campus or by the University. A conflict may also arise when the resources of the campus or University are utilized for research in a way that is incongruent with the mission, obligations, or values of the institution and that is for financial gain.

### **3. Principles**

The University of California adheres to the following institutional values:

- a. **Public Trust** – As a public institution, the University of California has a duty to disseminate knowledge for the public benefit and to maintain the public trust in the integrity of its efforts. Institutional decisions concerning financial matters should not undermine that trust.
- b. **Academic Mission** – The educational and research activities of the University of California should be motivated primarily by a concern for the advancement of knowledge and the betterment of society, not by the pursuit of financial reward.

- c. **Ethical Standards of Research** - The University of California's commitment to the highest ethical standards in research should not be weakened by financial relationships with outside institutions
- d. **Freedom to Pursue Research** – The freedom of researchers at the University of California to pursue areas of research and inquiry should not be constrained by financial relationships with outside institutions. Institutional financial relationships affecting research should operate to stimulate, not inhibit, research.
- e. **Objectivity in Research** – The process of scientific review and of determination of scientific merit should not be influenced by institutional financial relationships. There should be no connection between decisions concerning scientific merit and decisions concerning financial relationships with outside institutions.
- f. **Freedom to Publish** - The University of California must retain the freedom to publish and to disseminate research results. Financial relationships with outside entities and other economic activities of the University should preserve an open environment for the conduct of research at the University and for the dissemination of the results of research.
- g. **Freedom from Undue Influence on University Research Procedures** – The University of California's institutional financial relationships should not inappropriately influence internal research management decisions such as contracting, vendor sourcing, and assignment of resources.
- h. **Protection of Interests and Goals of Students** - The interests and goals of students must not be compromised for the benefit of institutional financial relationships. Student efforts to conduct research, publish results, and pursue academic inquiry must be paramount to the demands or desires of institutional financial partners.
- i. **Open Communication** – Communication between and among faculty, investigators, students, and staff at the University of California should not be subject to restrictions or limitations imposed by institutional financial relationships.

#### 4. **The University of California as a Public Institution**

The University of California is a public academic research institution and is subject to statutes and regulations concerning disclosure and management of financial interests with which all state agencies must comply. These rules and regulations require the disclosure by high-level University officials of financial interests and investments. This disclosure serves to regularly prompt University officials to consider their financial interests in the context of their leadership positions and to remind them of their duty to avoid financial interests that may be actual or apparent conflicts of interest. The disclosure also makes their financial interests available for review and scrutiny by University compliance and audit officers, regulators, and the public.

- a. **The California Political Reform Act of 1974, Gov. Code, § 81000 et seq.**  
The Political Reform Act requires designated officials to publicly disclose their financial interests on an annual basis. Designated officials are individuals holding leadership positions that involve financial decisions. Among the designated officials at UC who make annual financial interest disclosures are the Regents, the President, Vice Presidents, Provost, Vice Provosts, Assistant Vice Provosts, Associate Vice Provosts, Chancellors, Assistant

Chancellors, Associate Chancellors, Vice Chancellors, Assistant Vice Chancellors, Associate Vice Chancellors, Deans, Associate Deans, Directors, Executive Directors, Associate Directors, Managers, Auditors, Counsel, Chief Executive Officers, Chief Information Officers, Chief Medical Officers, Chief Operating Officers, Chief Administrative Officers, Contract and Grant Officers, Consultants. The Act also requires **all** UC employees to disqualify themselves from participating in official decisions in which they have a personal financial interest.

Although the PRA pertains to individual conflicts of interest, its application to high level University officials addresses the aspect of institutional conflict of interest wherein the financial interests of senior managers or trustees affect or may appear to affect institutional decisions to the detriment of the institution's mission.

**i. UC Conflict of Interest Code**

<http://www.ucop.edu/general-counsel/legal-resources/conflict-of-interest-code.html>

Under the Political Reform Act, the University must maintain a Conflict of Interest Code approved by the Fair Political Practices Commission, the state agency that oversees compliance with the Act. The University's Conflict of Interest Code has the force of law and a violation of the Code by a designated official is deemed a violation of the Political Reform Act. The UC Conflict of Interest Code prohibits the receipt of honoraria outside one's field of expertise, prohibits the receipt of gifts above a designated value, and requires economic interest disclosure by researchers conducting externally funded research. Finally the University's Conflict of Interest Code provides that no designated official shall make decisions or use their official position to influence decisions so as to benefit themselves personally.

**ii. The Academic Decision Regulation, 2 Cal.Code Regs. §18702.4(c)**

The Academic Decision Regulation is an implementing regulation of the Political Reform Act; its requirements are encompassed in the UC Conflict of Interest Code and implemented at the University through policy codified in the University's Academic Personnel Manual (APM-028 at <http://www.ucop.edu/acadpersonnel/apm/apm-028.pdf>). The Regulation requires principal investigators to disclose financial interests in non-governmental sponsors of research. If the investigator has a financial interest, the interest must be reviewed by an independent review committee to determine if the interest is significant enough to, or appear to, influence research decisions. Each UC campus has an independent review committee which reviews positive financial disclosures by UC researchers. In its review, the committee considers a number of factors to determine the extent of the conflict. These factors include: the size of the researcher's financial interest in the sponsor; the nature and duration of the researcher's relationship to the sponsor; the involvement of students; the nature of the research, e.g., whether the research contributes to the university's mission; whether the potential public benefits to be gained from undertaking the research outweigh any potential erosion of academic freedom or public trust. The review committee determines whether the financial interest amounts to a conflict of interest and what conditions or management strategies should be applied in order to eliminate any significant negative impact on the research.

**5. University of California Policies and Measures**

The following policies, structure and training requirements pertaining to institutional conflict of interest in research are in effect at the University of California.

**a. Policy on Accepting Equity When Licensing University Technology**

The University's policy on accepting equity when licensing University technology provides guidance regarding the conditions under which University may accept equity in a company as partial consideration for receiving a license. The policy requires acceptance of equity to be based upon principles of openness, objectivity and fairness in decision-making, guided by the mission of the University of education, research, and public service, and conducted in accordance with University policies on conflict of interest, integrity in research, and related University policies and guidelines.

- The text of the University's Policy on Accepting Equity when Licensing University Technology may be accessed at the following url:  
<http://policy.ucop.edu/doc/2500486/>
- University licensing guidelines may be accessed at the following url:  
[http://www.ucop.edu/research-policy-analysis-coordination/files/licensing\\_guidelines\\_2012.pdf](http://www.ucop.edu/research-policy-analysis-coordination/files/licensing_guidelines_2012.pdf)
- The University's systemwide form for providing information required for approval to accept equity may be accessed at the following url:  
<http://policy.ucop.edu/doc/2500486/>

**b. Structural Separation Between Financial Decisions and Research Decisions**

Institutional investment decisions at UC are made by the Treasurer's Office which manages the University's investment portfolio and retirement funds. There is no communication between the Treasurer's Office and the offices or officials connected with research decisions or research administration on the campuses or at the Office of the President concerning the conduct of research at UC, the type or nature of research to undertake, or the source of research funding. This structural separation creates a virtual divide between research decisions and financial decisions and is an effective firewall against the influence of institutional financial interests on research decisions.

**c. Training on Conflict of Interest**

The University of California provides online training on ethics, general conflict of interest principles, and issues specific to research.

**i. Ethics Training**

The ethics training is a 30-minute online course that covers the University's Statement of Ethical Standards and Standards of Ethical Conduct, documents approved by The Board of Regents in May 2005. The briefing is intended for all UC employees including designated officials such as Regents, the President, Vice Presidents, Provost, Vice Provosts, Assistant Vice Provosts, Associate Vice Provosts, Chancellors, Assistant Chancellors, Associate Chancellors, Vice Chancellors, Assistant Vice Chancellors, Associate Vice Chancellors, Deans, Associate Deans, Directors, etc.

**ii. Conflict of Interest**

Designated officials, including Regents, the President, Vice Presidents, Provost, Vice Provosts, Assistant Vice Provosts, Associate Vice Provosts, Chancellors,

Assistant Chancellors, Associate Chancellors, Vice Chancellors, Assistant Vice Chancellors, Associate Vice Chancellors, Deans, Associate Deans, Directors, take an online training course on conflict of interest principles.

**iii. Conflict of Interest in Research**

Researchers and individuals involved in the design, conduct or reporting of research at the University of California are required to undergo online training on conflict of interest in research. The training is intended to satisfy funding agency requirements to train researchers on conflict of interest in the research setting.

**d. Disclosure of Investigator and Institutional Financial Interests in Human Subjects Research**

Investigators must disclose to the IRB all existing financial interests in the research as a part of their initial IRB submission, continuing review submissions and at any time the investigators' interest changes. The IRB (or IRB Chair/designee) will evaluate whether a disclosed interest needs to be included in the informed consent document.

With respect to disclosing institutional financial interests on the informed consent form document, the University has provided model language that campuses may use in disclosing to human subjects relevant institutional financial interests related to campus licensing agreements for University inventions and University equity positions in licensees. See RPAC Memo 11-04, **Financial Interest Disclosure in the Research Consent Form** at the following url:

[http://researchmemos.ucop.edu/index.php/site/memoDetail/memo\\_id/RPAC-11-04](http://researchmemos.ucop.edu/index.php/site/memoDetail/memo_id/RPAC-11-04)

**e. Health Care Vendor Relations Policy**

University's Health Care Vendor Relations Policy establishes minimum standards for campus implementation of Health Care Vendor relationship policies. Campuses may implement stricter policies. This policy may be accessed at the following url:

<http://policy.ucop.edu/doc/5000433/HealthVendorRelations>

The University's Health Care Vendor Relations Policy specifies that all employees of the University of California are subject to the conflict-of-interest provisions of the Political Reform Act and to the University of California policies delineated in [Business and Finance Bulletin G-39](#) (Conflict of Interest Policy). The Health Care Vendor Relations Policy is intended to supplement the aforementioned provisions as follows:

**Gifts and Compensation Provided by Vendors:** Prohibits gifts from health care vendors to individuals. Provides alternative methods for health care vendors to support educational programs, provide samples for evaluation, and provide samples for low income patients.

**Interaction between Health Care Vendors and University personnel:** Implements patient confidentiality provisions and provides that Health Care Vendors may not make uninvited sales calls.

**Responsibilities of committees that oversee purchasing decisions:** This provision re-states current University of California policy without change.

**Vendor preceptorships:** New requirement that Health Care Vendor paid preceptorships (education programs) are to be conducted as either University courses or as Continuing Education courses.

**Publicity of industry support:** This provision re-states current University of California policy without change.

**Anti-kickback law:** This provision re-states current University of California policy without change.

**Education:** This provision requires training on Health Care Vendor interactions for all affected individuals.

**f. Health Care Fraud, Waste and Abuse**

The University of California (UC) has adopted policies and procedures to prevent and detect violations of federal and state health care fraud, waste and abuse laws, including the federal Anti-Kickback statute (42 USC 1320a-7b) and the federal anti-self referral law known as “Stark” (42 USC 1395nn and 42 CFR part 411, subpart J). UC employees and contractors are required to report known or suspected instances of fraud, waste, and abuse in accordance with the [UC Policy on Reporting and Investigating Allegations of Suspected Improper Governmental Activities \(Whistleblower Policy\)](#).

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