

UC Davis Policy and Procedure Manual

Chapter 230, Sponsored Programs

Section 05, Individual Conflicts of Interest Involving Research

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Responsible Department: Office of Research

Source Document: University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Programs; Academic Personnel Manual Section APM-028, Disclosure of Financial Interest in Private Sponsors of Research.

Exhibit A, Procedures for Reporting, Reviewing, and Managing Conflicts of Interest in Research

I. Purpose

This policy establishes standards and procedures to ensure that the design, conduct and reporting of sponsored research and educational activities will not be compromised by any conflicting financial interest on the part of the principal investigator(s) or key personnel by implementing a system for the disclosure, evaluation, and management, reduction, and/or elimination of potential conflicts of interest. This policy complies with state disclosure requirements (Cal. Admin. Code, Title 2, § 18705) and federal regulations regarding objectivity in research (21 C.F.R. Part 54, 42 C.F.R. Part 50 and 45 C.F.R. Part 94).

II. Definitions

- A. Conflict of interest—a situation that occurs when the conduct of research could be compromised or appear to be compromised by a related financial interest of the principal investigator or key personnel.
- B. Financial interest—includes any of the interests in a private sponsor of research defined by the California Code of Regulations, Title 2, Section 18755 (http://www.fppc.ca.gov/index.html?id=247&r_id=/legal/regs/18755.htm), held by the principal investigator or the principal investigator's spouse, domestic partner and/or dependent children within the 12 months prior to the date of the offer of research funding.
- C. Key personnel—any person, other than the principal investigator, who is responsible for the design, conduct or reporting of sponsored research or educational activities conducted in whole or in part at the University.
- D. Management plan—the written plan for the management, reduction or elimination of a potential or actual conflict of interest.
- E. Principal Investigator—the investigator primarily responsible for the design, conduct or reporting of sponsored research or educational activities conducted in whole or in part at the University.
- F. Research—a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).
- G. Significant financial interest—anything of significant monetary value, including but not limited to salary or other payments for services; equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); or holding a position as an officer, director, agent, or employee of a business entity. "Significant financial interest" includes such interests held by a principal investigator or key personnel and by their spouses, domestic partners and/or dependent children.

Significant financial interest does NOT include:

- 1. Salary, royalties, or other remuneration from the University.

2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
 3. Income from service on advisory committees or review panels for public or nonprofit entities.
 4. An equity interest in a public company that represents less than a 5% ownership interest and less than \$10,000 in value as determined through reference to public prices.
 5. Annual salary, royalties or other payments from any source other than those referenced in subparagraphs (1) and (2) above that individually or when aggregated do not exceed \$10,000 over twelve months.
 6. Income from mutual funds and/or pension funds;
 7. A percentage of income received from the Veteran's Administration Medical Center as part of physician reimbursement for University faculty;
 8. Interest in a business entity if the business entity is an applicant for Phase I support under the Small Business Innovation Research (SBIR) Program.
- H. Small Business Innovation Research (SBIR) Program—the extramural research program for small businesses established by the awarding components of certain Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

III. Policy

- A. When a research project is sponsored by a nongovernmental entity:
1. All principal investigators must disclose their financial interests in the sponsor of the research.
 2. If the project involves human subjects, principal investigators and key personnel must disclose any significant financial interests related to the research project or that could reasonably appear to be affected by the sponsored research project.
- B. For research programs and educational activities sponsored by the federal government, University of California, and certain other entities (see list at <http://research.ucdavis.edu/home.cfm?id=OVC,10,1754,1152>), principal investigators and key personnel must disclose their significant financial interests that are related to the sponsored research project or educational activities or that could reasonably appear to be affected by the sponsored research project or educational activities.
- C. When it is determined that a sponsored research project may reasonably appear to be affected by a financial interest disclosed pursuant to III.A or III.B, the University shall take steps to reduce, manage or eliminate the conflict to assure objectivity.

IV. Prohibited Activities

The following activities are prohibited because they present conflicts of interest that are contrary to the University's central mission:

- A. Academic Freedom Restrictions
1. Investigators may not enter into secrecy or confidentiality agreements if the agreement:
 - a. Impacts the evaluation of a student, faculty member, or other employee.
 - b. Delays the protection of intellectual property rights or the fulfillment of degree requirements by more than the time contractually allowed for pre-publication review.

2. Investigators may not agree to arrangements that permit a sponsor to interfere in the scientific analysis or publication of research results or conclusions.
3. Professional evaluation of faculty, postdoctoral appointees, or staff, or academic evaluation of students may not be based upon participation in (or refusal to participate in) a principal investigator's or key personnel member's outside activities as defined by APM 025.

B. Human Subjects Research

1. Principal investigators and key personnel involved in research with human subjects may not:
 - a. Directly or indirectly accept any gifts or payments from the sponsor of the research except for payments that are commensurate with their efforts on behalf of the sponsor.
 - b. Buy or sell common stock (as opposed to mutual funds) in the sponsor of the research until their involvement in the research ends and the results of the research are published or otherwise disseminated to the public.
2. Principal investigators and key personnel involved in research with human subjects may not perform clinical trials or testing on licensed-products for companies in which the University holds equity as part of a licensing-related transaction where the technology was developed at UC Davis, except as permitted in Business and Finance Bulletin G-44.

C. Intellectual Property

1. An employee who is involved in negotiating a license on behalf of the University may not have a significant financial or other interest in the business entity that is a party to the negotiations, except as permitted in Business and Finance Bulletin G-44.
2. An employee shall not accept a position on the board of directors of a licensee in which the University holds an equity interest, except as permitted in Business and Finance Bulletin G-44.

V. Requirements for the Disclosure of Financial Interests

- A. All principal investigators and key personnel must disclose their financial interests and the interests of their spouses/domestic partners and dependent children on the appropriate disclosure form(s) as indicated in Exhibit A.
- B. All principal investigators and key personnel involved in projects sponsored by the federal government must update their financial interests and the interests of their spouses/domestic partners and dependent children at least annually.

VI. Roles and Responsibilities

A. Conflict of Interest Committee

1. The Conflict of Interest Committee shall review the positive disclosures of financial interests from principal investigators and key personnel to determine if a conflict of interest exists, and if so, how to manage, reduce, or eliminate the conflict as described in Exhibit A.
2. The Conflict of Interest Committee members are appointed by the Vice Chancellor–Research for three year terms.
3. The Committee shall be comprised of 11 voting members to include faculty members from the School of Medicine, the College of Agricultural and Environmental Sciences, the College of Engineering, the School of Veterinary Medicine, the College of Biological

Sciences, and the College of Letters & Science, and one at-large member. The Committee shall have four non-voting, ex-officio participants including the Director—Sponsored Programs, the Director — Institutional Review Board, the Director—Research Compliance, and the Associate Campus Counsel. Other non-voting ‘ad-hoc’ participants may assist in discussions and decisions as needed.

4. Recusal

A committee member shall be recused from discussion and voting on a particular case if:

- a. The committee member has a compelling personal interest in the case (such as research or academic collaboration with the individual whose case is under consideration); or
- b. The committee member has a financial interest in the case under consideration.

B. Director—Research Compliance

The Director—Research Compliance is responsible for supporting the Conflict of Interest Committee, the individual monitors, and the Management Sub-Committees, ensuring that the Committees’ decisions, recommended actions and reasons therefore are fully documented and implemented, and that the University complies with its obligations under state and federal law and this policy.

C. Director—Sponsored Programs

The Director—Sponsored Programs is responsible for ensuring that no federal funds are expended before the federal sponsor receives notification when it is determined that a conflict of interest exists.

D. Institutional Review Board (IRB)

1. The IRB will not approve any research involving human subjects where the principal investigator or a key personnel member has submitted a positive financial disclosure until the Conflict of Interest Committee reviews the disclosure and provides its recommendations to the IRB.
2. The IRB will review recommendations it receives from the Conflict of Interest Committee regarding the management, reduction or elimination of conflicts of interest to ensure that the recommended course of action will adequately protect study participants and the credibility of the human research protection program.

E. Principal investigators are responsible for the following:

1. Disclosing financial interests as required by this policy and Exhibit A.
2. Ensuring disclosure by key personnel when required by this policy and Exhibit A.
3. Complying with the provisions in Section F, below.

F. Principal investigators and key personnel are responsible for the following:

1. Disclosing financial interests when required by this policy and Exhibit A.
2. Upon request, preparing a statement for an individual monitor or management sub-committee regarding how they intend to manage, reduce, or eliminate a conflict when it is determined to be necessary by the Conflict of Interest Committee.
3. Cooperating with the Conflict of Interest Committee and any monitor or management sub-committee in providing reports and documents as requested.
4. Conducting the sponsored research or educational activity in a manner that will avoid a perception that the project could be influenced or biased by conflicts of interest.

5. Fulfilling all conditions necessary to manage a conflict of interest as determined by the Conflict of Interest Committee, a monitor or management sub-committee, and in the case of research involving human subjects, the IRB.

VII. Records

A. Confidentiality

California State Form 700-U is a public record. All other records and information provided by a principal investigator and key personnel for the purpose of disclosure and management of a research conflict of interest and all official records of disclosure and management of a conflict of interest shall be considered personal information as described in Section 320-20. The unauthorized disclosure of any such information by an employee, except as required for official business purposes or by law, shall be grounds for discipline under Section 320-20.

B. Records Retention

Official records regarding individual conflicts of interest shall be maintained by the Office of Research and retained for 7 years or as otherwise required by state and federal law.

VIII. Violations

- A. Failure to file disclosures or provide information required by this policy or to comply with any conditions or restrictions imposed by the Conflict of Interest Committee, a monitor, or management sub-committee constitute violations of this policy, which may be grounds for discipline pursuant to the appropriate University, state and federal policies.
- B. State and/or federal regulations may require reports to the project sponsor regarding violations of this policy. Project sponsors may impose additional sanctions including the suspension or termination of an award or debarment from receiving future awards.

IX. Further Information

Questions about this policy and the procedures should be directed to the Director—Research Compliance in the Office of Research.

X. References

A. UC Office of the President:

1. UC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects, 10/15/97.
2. UC Conflict of Interest Code.
3. UC Standards of Ethical Conduct.
4. Business and Finance Bulletins:
 - a. G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest.
 - b. G-44, Guidelines on Accepting and Managing Equity When Licensing University Technology.
 - c. BUS-78, A Guide to the Political Reform Act of 1974.

B. Academic Personnel Manual:

1. Section APM-015, Faculty Code of Conduct; and UCD-015, Procedures for Faculty Misconduct Allegations.
2. Section APM-016, University Policy on Faculty Conduct and the Administration of Discipline; and UCD-016, Procedures for Faculty Discipline.

3. Section APM-025 and UCD-025, Conflict of Commitment and Outside Activities of Faculty Members.
 4. Section APM-028, Disclosure of Financial Interest in Private Sponsors of Research.
 5. Section APM-140 and UCD-140, Non-Senate Academic Appointees/Grievances.
 6. Section APM-210-1, Appendix A, Statement on Professional Ethics.
- C. Academic Senate Bylaw 335, Privilege and Tenure: Divisional Committees—Grievance Cases (May 23, 2001), and Davis Division Bylaw 87, Privilege and Tenure.
- D. Personnel Policies for Staff Members:
1. UC Policy 62 and UCD Procedure 62, Corrective Action—Professional and Support Staff.
 2. UC Policy 64 and UCD Procedure 64, Termination of Career Employees—Professional and Support Staff.
 3. UC Policy 65 and UCD Procedure 65, Termination of Career Employees—Managers and Senior Professionals, Salary Grades I through VII.
 4. UC Policy 67, Termination of Career Employees—Managers and Senior Professionals, Salary Grades VIII and IX.
 5. UC Policy 70 and UCD Procedure 70, Complaint Resolution.
 6. UC Policy 71, Resolution of Concerns—Managers and Senior Professionals, Salary Grades VIII and IX.
 7. UC Policy 82 and UCD Procedure 82, Conflict of Interest.
 8. UC Appendix II, Personnel Policies for Senior Managers.
- E. UC/union collective bargaining agreements <http://www.hr.ucdavis.edu/Elr/Contracts>
- F. UC Davis Policy & Procedure Manual:
1. Section 250-15, Patents.
 2. Section 320-20, Privacy of and Access to Information.
 3. Section 380-16, Conflict of Interest.
 4. Section 380-17, Improper Governmental Activities.
 5. Section 380-55, Acceptance of Offering of Gifts and Gratuities by University Employees.
- G. UC Davis Health System Hospital Policies and Procedures
1. Section 1705, Conflict of Interest.
 2. Section 2204, Vendor Relationships.
- H. Federal Laws and Regulations:
1. Code of Federal Regulations
 - a. Title 21, Part 54, Financial Disclosure by Clinical Investigators.
 - b. Title 42, Part 50, Section 50.604, Institutional Responsibility Regarding Conflicting Interests of Investigators.
 - c. Title 45, Part 94, Responsible Prospective Contractors.
 2. U.S. Code Title 41, Sections 51-58, Anti-Kickback Act of 1986.
 3. OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements

With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.

- I. California State Laws and Regulations:
 1. Government Code Section 81000 et. seq., Political Reform Act.
 2. California Code of Regulations, Title 2, Division 6, Section 18110 et. seq., Regulations of the Fair Political Practices Committee.