
UCLA Procedure 925.2: Disclosing Financial Interests in Non-Governmental Sponsors of Contracts, Grants, and Material Transfer Agreements for Research

Issuing Officer: Vice Chancellor for Research
Responsible Dept: Office of Research Administration
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I. PURPOSE AND SCOPE

State of California regulations require that Principal Investigators (PIs) disclose personal financial interests in non-governmental sponsors of research. Additionally, UCLA policy requires that all Investigators on a project who share responsibility for the design, conduct, or reporting of the research disclose certain personal financial interests in non-governmental sponsors.

This procedure describes the conditions under which these financial interests should be disclosed. For more information on applicable State regulations and related campus policies concerning conflicts of interest, see section V, below.

II. DEFINITIONS

Investigator: For purposes of this procedure, any UCLA employee who shares responsibility for the design, conduct, or reporting of the results of a sponsored project.

Principal Investigator (PI): A UCLA employee (normally an academic appointee) who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

Financial Interest: As used in this procedure, based on definitions and thresholds for reporting taken from the California Political Reform Act of 1974, means anything of monetary value including, but not limited to:

- A position as director, officer, partner, trustee, employee, or any other position of management in the sponsor; and/or
- Income from the sponsor (including, but not limited to salaries and wages, consulting income, honoraria for services performed, per diem, reimbursement for expenses, rental income, dividends and interest, and proceeds from sales) including income deposited into, or payments made directly to a health sciences compensation plan aggregating \$500 or more in value received by or promised within 12 months prior to the time the award is made; and/or
- An investment including stocks, bonds, warrants, and options, including those held in margin or brokerage accounts, in the sponsor worth more than \$2,000; and/or
- A gift of \$50 or more, or multiple gifts totaling \$50 or more, from the sponsor, received by or promised to the researcher within 12 months prior to the time the award is made; and/or

- Loans from the sponsor for which the outstanding balance has exceeded \$500 in the past 12 months.

Significant Financial Interest: As used in this procedure, based on definitions that reflect the National Science Foundation policy on objectivity in science, and on federal reporting thresholds, means anything of monetary value including, but not limited to:

- Income including salary, consulting payments, honoraria, reimbursement of expenses, royalty payments, dividends, loans from an entity, or any other payments or consideration of value, including payments made to a health sciences compensation plan, during the prior twelve months or anticipated in the next twelve months, of \$10,000 or more;
- Equity in the form of stock, stock options, warrants, real estate, loans to or from an entity, or any other investment or ownership interest exceeding *either* \$10,000 (current market value if publicly traded; otherwise, amount of investment) *or* a 5% ownership interest, for any one enterprise;
- A management position, whether paid or unpaid, such as board member, director, officer, partner, or trustee;
- Intellectual property interest on a patent, patent application, or copyright assigned or licensed to a party other than The Regents.

III. DISCLOSURE OF FINANCIAL INTERESTS

In accordance with State of California regulations and UCLA Policy 925, a Principal Investigator (PI) must disclose his or her Financial Interests, and other Investigators must disclose Significant Financial Interests, if a research project is supported in whole or in part by a non-governmental entity. Reporting of Financial Interests is required for the individual, his or her spouse or registered domestic partner, and any dependent children. Support for research includes funding or provision of equipment or materials needed to conduct a research project and can be received as contracts and grants (including cooperative agreements) and material transfer agreements.

Financial Interests disclosed in conjunction with receipt of research support are reviewed by the UCLA Conflict of Interest Review Committee (CIRC). After review, the CIRC will determine whether the disclosed Financial Interests (for PIs) or Significant Financial Interests (for all other Investigators) reasonably appear to directly and materially affect the design, conduct, or reporting of projects and thereby constitute a conflict of interest that may need to be managed, reduced, or eliminated before support for the research can be accepted by the campus.

Certain sponsoring organizations are exempt from the reporting requirements (for a list of exempt organizations, see <http://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/conflict-of-interest/list-of-non-governmental-entities-exempt-from-disclosure-requirement.html>). In addition to the institutions named on the list, “all non-profit, tax-exempt educational institutions” are exempt. Private, non-profit colleges and universities are among the exempt organizations.

Other Circumstances Under Which Disclosures Must be Made

On occasion the PI and other Investigators may have to submit multiple disclosures. If the University’s agreement is with a contract research organization or other intermediary working for a study sponsor, disclosure of Financial Interests in *both* organizations is required. If the study sponsor is not the manufacturer(s) of the product(s) being tested, then disclosure of Financial Interests in the manufacturer(s) of the drug(s) or device(s) is *also* required.

If materials (e.g., drugs, devices, equipment, reagents, cell lines, animals, etc.) being tested or used as tools in the research are being provided by a for-profit or not-for-profit organization for use in a project being funded by the federal Public Health Service (PHS) or National Science Foundation (NSF), then

disclosure of Financial Interests in the organization that is providing the materials should be made under this procedure *as well as* under UCLA Procedure 925.3.

If the University is receiving a subcontract or a subgrant, then disclosures should be provided for *both* the organization with which the University is receiving the subcontract or subgrant, *and* the prime sponsor of the research.

A. When Must Disclosures be Made

Disclosures of Financial Interests and/or Significant Financial Interests must be made:

1. Each time a new proposal for research support is submitted to a *non-governmental (for-profit or not-for-profit) sponsor*;
2. Each time a request for additional support is submitted to a *non-governmental (for-profit or not-for-profit) sponsor*;
3. With each request for negotiation of a Material Transfer Agreement to procure materials from a for-profit or not-for-profit sponsor.

All information requested on the disclosure forms is mandatory. All reviews must be completed and if required, the sponsor notified before awards can be accepted.

B. Which Forms Should be Used

Under the State of California Political Reform Act of 1974, the PI must report Financial Interests using State Form 700-U. The PI must also complete a 700-U Addendum identifying all other Investigators who share responsibility for the design, conduct, or reporting of research, or indicating that there are no other Investigators on the project who share these responsibilities.

The PI and all other Investigators who disclose personal Financial Interests in a research sponsor should also complete a “Disclosure Supplement”, providing additional details. If the study is an industry supported clinical trial, the PI and all other Investigators who disclose personal Financial Interests should complete an “Industry Clinical Trial Specific Disclosure Supplement”.

C. Responsibilities of Collaborators and Consultants

1. All collaborators from other institutions, who share responsibility for the design, conduct, or reporting of research results are expected to comply with the policies and procedures for conflict of interest reviews at the institution at which they are employed.
2. Consultants who are affiliated with organizations that do not have their own conflict of interest review process may defer to UCLA’s procedures. In so doing, consultants agree to abide by any determinations that UCLA may make about the management, reduction, or elimination of Financial Interests or Significant Financial Interests.

IV. PROCEDURES

A. Completion of Forms 700-U, 700-U Addendum, and Disclosure Supplement or Industry Clinical Trial Specific Disclosure Supplement (for all forms see the UCLA Research Policy & Compliance Web site at <http://ora.research.ucla.edu/rpc/Pages/RPCHome.aspx>)

RESPONSIBILITY	ACTION
Principal Investigator (PI)	<p>Completes Form 700-U. If any Financial Interests are disclosed on the 700-U, also completes a Disclosure Supplement. If the study is a clinical trial, completes an Industry Clinical Trial Specific Disclosure Supplement <i>instead of</i> a regular Disclosure Supplement.</p>
	<p>Completes the 700-U Addendum. Solicits disclosures from all other Investigators listed on the 700-U Addendum. All disclosures can be collected on the same form, attaching additional copies as needed. Signs the 700-U Addendum certifying that all other Investigators required to make disclosures are listed on the form.</p>
All Investigators	<p>Sign the 700-U Addendum certifying that either no Significant Financial Interests exist, or that a complete listing of all Financial Interests is provided on an attached Disclosure Supplement form.</p>
	<p>All Investigators who have Financial Interests should also complete a separate Disclosure Supplement. If the study is a clinical trial, Investigators who have disclosed Financial Interests should also complete an Industry Clinical Trial Specific Disclosure Supplement <i>instead of</i> a regular Disclosure Supplement.</p>
PI	<p>Promptly forwards completed forms to the Office of Contract & Grant Administration (OCGA) with proposals for government/non-profit contracts and grants, to the Office of Clinical Trials (OCT) with proposals for industry supported clinical trials, or the Technology Development Group (TDG) in conjunction with other kinds of industry supported research and Material Transfer Agreements (MTA).</p>
Collaborators from Other Institutions	<p>Must comply with their employing institution's conflict of interest policies and procedures and have their institutions send assurance of review to OCGA, OCT, or TDG, as appropriate. These assurances should identify the contract/grant or MTA number, the name of the PI, the name of the Investigator with the Significant Financial Interest, whether the Significant Financial Interest was found to constitute a conflict of interest and if so, how that conflict of interest will be managed, reduced or eliminated. UCLA should also be notified if the reviewing institution determines that the conflict of interest cannot be managed. OCGA, OCT, or TDG staff who receive assurances from collaborating institutions should forward the original to the CIRC staff and retain a copy for the contract, grant or MTA file.</p>
OCGA, OCT, or TDG	<p>Ensures all necessary forms have been submitted and reviews them for completeness.</p>
	<p>If the Form 700-U indicates that the PI has no Financial Interests and the 700-U Addendum indicates either that there are no other Investigators on the project, or that no other Investigators have anything to disclose (i.e., a negative disclosure), retains originals in the proposal, award or MTA file as the office of record.</p>
	<p>If the Form 700-U indicates the PI has a Financial Interest and/or the 700-U Addendum indicates that any other Investigators have a Significant Financial Interest, ensures that those Investigators also complete Disclosure Supplement forms. Collects additional background information and clarification as needed to prepare a case for review by the CIRC prior to acceptance of the award.</p>
	<p>Contacts the CIRC staff and provides them with original disclosure forms and any additional materials and information as needed, retaining a copy for the proposal or award file. The CIRC will serve as the office of record for the materials that require review.</p>

RESPONSIBILITY	ACTION
CIRC	Reviews case materials. May also interview the PI, and/or other UCLA officials, and/or seek additional information, including, but not limited to, such items as prior approvals for compensated outside professional activities (as required under Academic Personnel Manual, Section 025), consulting agreements, or relevant sections of licensing agreements. Forwards to Vice Chancellor for Research the CIRC advice concerning whether or not the Financial Interest or Significant Financial Interest will directly and materially affect the project and, as appropriate, recommends action for managing, reducing or eliminating any real or perceived conflicts of interest.
Vice Chancellor for Research	Based on the CIRC review and recommendations, determines whether any action is needed to manage, reduce or eliminate conflicts of interest. Notifies PIs, other Investigators, and as appropriate, other campus officials of decision. Additional notification shall be sent to the Office for Protection of Research Subjects (OPRS) if human subjects are involved.
CIRC	If required, notifies the sponsor that a conflict of interest has been managed, reduced, or eliminated either at UCLA or at a collaborating institution; or advises that the conflicts of interest cannot be managed. Follows up as appropriate when plans to manage the conflict of interest have been put into place.

B. Access to Statements

Under California state law and University policies, completed financial disclosure forms and other information required under this procedure are available to any member of the public upon request. Sponsors may be notified about the disclosure and review of Financial Interests as required.

C. Sanctions

Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline pursuant to the University Policy on Faculty Conduct and the Administration of Discipline (Academic Personnel Manual, APM-016) and/or other applicable employee disciplinary policies.

V. RELATED POLICIES, REGULATIONS AND FORMS

1. UCLA Policy 150, Conflict of Interest.
2. Memorandum from Vice Provost Robert Shelton, February 4, 1997.
3. Disclosure of Financial Interest in Private Sponsors of Research, APM-028, dated 4/29/2010.
4. Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects, February 3, 1995.
5. UCLA Policy 925, Financial Conflicts of Interest in Research.
6. UCLA Procedure 925.3, Disclosing Financial Interests Relevant to Federally Sponsored Contracts and Grants for Research.
7. Academic Personnel Manual, APM-025 - Conflict of Commitment and Outside Activities of Faculty Members, revised July 1, 2001.
8. Academic Personnel Manual, APM-016 – University Policy on Faculty Conduct and the Administration of Discipline.
9. Academic Decisions Exception Regulation (California Code of Regulations, Title 2, §18702.4(c)(2)).

10. Political Reform Act of 1974 (California Government Code, Section 81000, et seq.).

For the following forms and list, see the UCLA Research Policy & Compliance Web site at:
<http://ora.research.ucla.edu/rpc/Pages/RPCHome.aspx>.

11. Form 700-U, “Statement of Economic Interests for Principal Investigators” and “Instructions for Completing Form 700-U”.
12. Form 700-U Addendum.
13. “Disclosure Supplement” to Form 700-U.
14. “Industry Clinical Trial Specific Disclosure Supplement”.
15. Sponsors of Research Exempted from University Non-Governmental Entity Financial Disclosure Requirement.

Issuing Officer

/s/ Roberto Peccei

Vice Chancellor for Research

**Questions concerning this policy or procedure should be referred to
the Responsible Department listed at the top of this document.**
