UCLA Procedure 925.3: Disclosing Financial Interests Related to Federally Sponsored Research Projects (except Public Health Service)

Issuing Officer: Vice Chancellor for Research
Responsible Dept: Office of Research Administration
Effective Date: December 11, 2012
Supersedes: UCLA Procedure 925.3, dated 8/24/2012

I. PURPOSE & SCOPE

Based on definitions and thresholds of Significant Financial Interests outlined within the National Science Foundation (NSF) “Investigator Disclosure Policy,” Investigators are required to disclose certain financial interests (defined below) to ensure that the design, conduct, or reporting of federally-funded projects will not be biased.

This Procedure describes the conditions under which these financial interests should be disclosed by Investigators. With the exception of the U.S. Public Health Service (including the National Institutes of Health (NIH)) that has issued separate regulations (see UCLA Policy 926), this Procedure will also be used to solicit and review disclosures by Investigators seeking support from all other federal agencies and by those other sponsors and programs that specifically require review consistent with these federal standards. For more information on applicable federal regulations and related campus policies concerning conflict of interest, see Section V., below.

II. DEFINITIONS

For the purposes of this procedure, the following definitions shall apply:

Conflict of Interest Review Committee (CIRC): A UCLA faculty committee charged with determining if Significant Financial Interests that are related to the proposed research constitute financial conflicts of interest and developing plans to eliminate, reduce, or manage financial conflicts of interest. The CIRC is appointed by the Chancellor and is advisory to the Vice Chancellor for Research.

Investigator: Any individual who shares responsibility for the design, conduct, or reporting of the results of a sponsored project with the Principal Investigator.

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

Significant Financial Interest: Based on definitions taken from NSF policy, anything of monetary value including, but not limited to:

- Salary or other payment for services including: consulting payments, honoraria, reimbursement of expenses, royalty payments, dividends, loans 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 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; or
- Intellectual property interest on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than The Regents.

Specifically excluded from the definition of Significant Financial Interest are payments made by The Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University. Also excluded is income for seminars, lectures, teaching engagements sponsored by public or non-profit entities, or service on advisory committees or review panels for public or nonprofit entities.

III. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

In accordance with University and UCLA policies, Investigators are required to disclose Significant Financial Interests as defined above. In all cases, reporting is required for the individual, his/her spouse or registered domestic partner, and any dependent children.

All Investigators must disclose:
- Any Significant Financial Interests that would reasonably appear to be affected by the research for which funding is sought; and/or
- Any Significant Financial Interests in entities whose financial interests (e.g., its earnings, value, sales of its products, etc.) would reasonably appear to be affected by the research.

Disclosures of Significant Financial Interests will be reviewed by an official or officials designated by the Vice Chancellor for Research to determine whether the financial interests reasonably appear to directly and materially affect the design, conduct, or reporting of projects and thereby constitute a financial conflict of interest that may need to be managed, reduced, or eliminated prior to the expenditure of any funds under the award. Most of these reviews are conducted by the CIRC.

A. Who Must Disclose Significant Financial Interests

1. All UCLA Investigators who share responsibility for the design, conduct or reporting of the research results must disclose Significant Financial Interests to UCLA.

2. Collaborators from other institutions who share responsibility for the design, conduct, or reporting of research results, and who will be conducting research under a sub-grant or subcontract from UCLA are expected to comply with the policies and procedures for disclosure and review of any Significant Financial Interest at the institution at which they are employed. Those institutions are responsible for reviewing those disclosures and, if conflicts are identified, for sending UCLA assurances of their ability to manage, reduce, or eliminate the conflicts.

3. Collaborators who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by UCLA should be identified as Investigators by the UCLA PI and should complete the UCLA disclosure forms. If, upon review, UCLA determines that these financial interests could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce, or manage the identified conflicts of interest.

B. When Disclosures Must be Made

Disclosures of Significant Financial Interests must be made:
- Each time a request for new funds is submitted to NSF or another federal agency or sponsor covered by this Procedure;
- Any time a new Investigator is added to an ongoing project subject to this Procedure; and
- Any time during the term of an ongoing award (including periods covered by no-cost time extensions) that an Investigator acquires a new Significant Financial Interest that was not reported on the original disclosure form.
Examples of situations in which Significant Financial Interests should be disclosed include, but are not limited to:

- An Investigator is conducting a sponsored project where the results could be relevant to the development, manufacturing or improvement of the products or services of an entity in which the Investigator has a Significant Financial Interest.

- An Investigator has a Significant Financial Interest in an entity, which might manufacture or commercialize a drug, device or procedure that might result from the sponsored project; or which manufactures or sells any product that will be tested or used in the sponsored project, or that would reasonably appear to be affected by the research.

- An Investigator has a Significant Financial Interest in an entity, which manufactures or sells a concomitant or comparator drug, device, or procedure, and would reasonably appear to be affected by the research.

- An Investigator received consulting income that exceeded $10,000 from any entity during the prior 12 months or anticipates receiving income of $10,000 or more over the next 12 months, and the financial interests of that entity would reasonably appear to be affected by the research.

- An Investigator has a Significant Financial Interest in an entity to which a portion of the work under the project will be subcontracted, from which space will be leased, to which participants will be referred, or from which purchases will be made.

- An Investigator is carrying out a sponsored project and has a Significant Financial Interest in an entity that is part of a consortium or that will otherwise participate in the sponsored project.

In accordance with NSF policy, all disclosures must be received by the UCLA Office of Contract & Grant Administration or the Office of Intellectual Property & Industry Sponsored Research before the proposal for funding can be submitted to the agency. All reviews must be completed and any identified conflicts of interest managed, reduced, or eliminated before award funds can be expended.

Significant Financial Interests disclosed to UCLA under this Procedure will be reviewed either by the CIRC or a designated official.

Under NSF policy, UCLA must notify the sponsor if, upon review, it is determined that an actual or potential conflict of interest cannot be managed.

IV. PROCEDURES

A. Completion and Review of Disclosure Forms

<table>
<thead>
<tr>
<th>RESPONSIBILITY</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator (PI)</td>
<td>Identifies all other Investigators who share responsibility for the design, conduct or reporting of the research or educational activities.</td>
</tr>
<tr>
<td></td>
<td>Completes the upper portion of Form 740 (see section V.9., below) as well as line 1 of the “Disclosure and Certification” section, and uses lines 2-5 to provide the names of all other UCLA Investigators and Consultants who share responsibility for the design, conduct, or reporting of the research (or educational activities for NSF funding) including those who join ongoing projects.</td>
</tr>
<tr>
<td></td>
<td>Signs Form 740 certifying that all other Investigators required to make disclosures have been listed on the form.</td>
</tr>
<tr>
<td></td>
<td>Reminds all Investigators of their ongoing responsibility to provide updated information if they obtain any new Significant Financial Interest(s) during the term of the award.</td>
</tr>
<tr>
<td>RESPONSIBILITY</td>
<td>ACTION</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
</tr>
<tr>
<td>All Investigators</td>
<td>Complete and sign Form 740 certifying that either no Significant Financial Interest exists or that a complete listing of all financial interests is provided on a completed and signed Disclosure Supplement form (see section V.10., below). In signing Form 740, all individuals also acknowledge their responsibility to disclose any new Significant Financial Interest(s) obtained during the term of the award.</td>
</tr>
<tr>
<td>PI</td>
<td>Promptly forwards completed forms to the Office of Contract &amp; Grant Administration (OCGA), or Office of Intellectual Property &amp; Industry Sponsored Research (OIP-ISR) as appropriate.</td>
</tr>
<tr>
<td>Collaborators working on the project under sub-grants or subcontracts with other institutions</td>
<td>Must comply with their employing institution’s policies and procedures on completion and review of financial disclosures, and have their institutions send assurance of review to OCGA or OIP-ISR. These assurances should identify the proposal/contract/grant number, the name of the UCLA 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. The UCLA Subaward Administrator should also be notified if the reviewing institution determines that the conflict of interest cannot be managed.</td>
</tr>
<tr>
<td>Collaborators working on the project as Independent Consultants</td>
<td>Must be identified as Investigators by the UCLA PI and should be asked to complete the UCLA disclosure forms. If, upon review, UCLA determines that these financial interests could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce, or manage the identified conflicts of interest.</td>
</tr>
<tr>
<td>Office of Contract &amp; Grant Administration (OCGA) or Office of Intellectual Property &amp; Industry Sponsored Research (OIP-ISR)</td>
<td>Ensures all necessary forms have been submitted and reviews for completeness. Forwards to Conflict of Interest Review Committee (CIRC) staff any assurances received from collaborating institutions. If Form 740 indicates that neither the PI nor other Investigators have any Significant Financial Interests to disclose (a negative disclosure), retains original in the proposal or award file, as the office of record. If Form 740 indicates that the PI or any other Investigators have a Significant Financial Interest (a positive disclosure), ensures that those Investigators with Significant Financial Interests have also completed 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. Provides CIRC staff with original disclosure forms and any additional materials and information as needed, retaining a copy for the proposal or award file. The Office of the Vice Chancellor for Research will serve as the office of record for the materials that require review.</td>
</tr>
<tr>
<td>Institutional Review Board (IRB) or California Institute of Regenerative Medicine (CIRM)</td>
<td>Forwards requests for CIRC review to CIRC staff on an as-needed basis.</td>
</tr>
<tr>
<td>Designated Official (DO)</td>
<td>Conducts a preliminary review of all positive Investigators’ Statements of Financial Interests to determine if full review by the CIRC is required. Confers with the CIRC Chair and the Vice Chancellor for Research about which Investigators’ Statements of Financial Interests may be processed without full CIRC review. If after review it appears that the reported Significant Financial Interest(s) will not directly and materially affect the design, conduct, or reporting of the project and/or if the Significant Financial Interest(s) disclosed have been previously reviewed by the CIRC, confers with the CIRC Chair and forwards a recommendation of action to the Vice Chancellor for Research.</td>
</tr>
<tr>
<td>CIRC</td>
<td>Reviews case materials. May also interview the PI and/or other UCLA officials, and/or seek additional information.</td>
</tr>
</tbody>
</table>
### RESPONSIBILITY ACTION

<table>
<thead>
<tr>
<th>RESPONSIBILITY</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIRC (cont'd)</td>
<td>Forwards to the Vice Chancellor for Research the CIRC determination about whether or not the financial interest will directly and materially affect the project, and recommendations intended to manage, reduce, or eliminate any real or perceived financial conflicts of interest.</td>
</tr>
<tr>
<td>Vice Chancellor for Research</td>
<td>Based on the DO or the CIRC review and recommendations, determines whether any action is needed to manage, reduce, or eliminate financial conflicts of interest.</td>
</tr>
<tr>
<td>Office of the Vice Chancellor for Research</td>
<td>If required, provides sponsor with notification that a Significant Financial Interest has been identified at UCLA or at a collaborating site and, as specified by the sponsor, either provides assurance that the conflict of interest has been managed, reduced, or eliminated, or advises that the conflict of interest cannot be managed.</td>
</tr>
</tbody>
</table>

**B. Access to Statements and Disclosure of Information**

The information provided in disclosure forms may be released or transmitted to the sponsor upon request. Under the California Public Records Act, this information may be made available to the public upon request.

**C. Record Retention**

Records of financial disclosures, Designated Official’s determination, CIRC recommendations, and University action regarding management of a conflict of interest will be retained for at least three years beyond the termination or completion of an award (at least three years from the date of submission of the final expenditures report, or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report), or until the resolution of any action by the sponsor involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

**D. Sanctions**

Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, 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 or student disciplinary policies. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. Similarly, an agreement with a sub recipient may be terminated for cause if the sub recipient fails to comply with the obligations to implement and maintain a conflict of interest policy. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and University policy. If an Investigator’s failure to comply with this policy has biased the design, conduct, or reporting of federally supported research, the Office of the Vice Chancellor for Research will promptly notify the appropriate agency of the corrective action taken or to be taken.

**V. RELATED POLICIES, REGULATIONS & FORMS**

1. UCLA Policy 925, Financial Conflicts of Interest in Research;
2. UCLA Policy 926, Public Health Service Regulations on Objectivity in Research;
5. California Public Records Act (Government Code § 6250 et seq.);
7. UC Business & Finance Bulletin, RMP-2, Records Retention and Disposition;
8. UCOP Memo on Administrative Records Relating to Research: Retention Disposition and Requirements, September 26, 2006;

Issuing Officer

/s/ James S. Economou

Vice Chancellor for Research

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