

Policy on Conflict of Interest in Externally Funded Research

I. General

- A. This policy sets institutional Conflict of Interest standards and practices applicable to Investigators. This policy is intended to strengthen, and where appropriate, be interpreted consistent with the CSU Conflict of Interest Code. See California Government Code 87300.

The term “Investigator” means the Principal Investigator, Co-Investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research activities funded or proposed for funding. It is the responsibility of the Principal Investigator to identify all persons with such design, conduct or reporting responsibilities, whether or not they are identified in the proposal, grant or contract, and ensure that they follow the provisions of this policy.

- B. Investigators, and others as required, will disclose to the responsible representative of the institution all significant financial interests of the Investigator (including those of the Investigator’s spouse and dependent children) (i) that would reasonably appear to be affected by the activities funded or proposed for funding, or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.
- C. The Vice President for Academic Affairs shall be the President’s designee for ensuring compliance with this policy.
- D. The Director of Grants Development shall provide a copy of this policy statement to Investigators at the time of application for a project to be sponsored through a grant or contract. Instructional deans and advancement officers will provide a copy of this policy statement to faculty who are requesting or have received a restricted gift for research.
- E. Department chairs and Deans/Directors of administrative units shall disqualify themselves from approving a research proposal for a project to be funded in whole or in part by an entity in which they have a financial interest.
- F. Investigators must provide to the Grants Development Office all required financial disclosures at the time a proposal is submitted to any potential funding agency/sponsor, or to the University Advancement Division when a gift is requested or anticipated. Investigators must update those financial

disclosures during the pendency of the award, on an annual basis, or as new reportable significant financial interests are acquired during the course of the project. The Investigator must complete the “Investigator’s Statement of Economic Interest” and other required disclosure statements (1) whenever he/she makes application for a new or renewal contract or grant, or (2) whenever a gift is specified by a donor for a specific Investigator or for a specific project for which the Investigator is responsible. The disclosure must be made before the proposed gift is accepted or application for funding is made for a new or renewed project or grant. The activity may not proceed without completion of the financial disclosure statement. An “Investigator’s Statement of Economic Interests” form must be filed again within 90 days after the gift funds are exhausted, or the project is completed.

- G. The “Investigator’s Statement of Economic Interests” (700U) is to be completed for all research projects that have been or will be funded, in whole or in part, by a non-governmental organization (NGO) (excepting those NGOs currently considered exempt; see www.ucop.edu/research/policies/exempt.html for current list), in the following two circumstances:

- (1) when the project is funded through a contract or grant, or
- (2) when the project is funded through a gift earmarked by the donor for a specific purpose or a specific individual

Alternatively, the “Disclosure of Financial Interests Related to Sponsored Projects” (800U) must be completed, if required by the sponsoring agency, in the case of federal grants and contracts.

- H. The Director of the Grants Development Office will review each disclosure to determine whether there is a risk that significant negative consequences might result from a disclosed conflict of interest. This determination will be based only on the information provided by the investigator and will be made in consultation with the Dean of Research and Graduate Programs, following specific guidance provided periodically by the Conflict of Interest in Research Committee (CIRC), a standing committee (see Article II.). When a disclosure indicates that such risk might exist, a substantive review of the disclosure statement and project shall be undertaken by the CIRC, prior to expenditure of any funds under the subject contract, grant, or gift. The CIRC will review financial disclosures and project documents to determine whether an actual or potential conflict of interest exists, and what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflicts of interest and the potential negative consequences that might result from them. A conflict of interest exists when the reviewer(s) reasonably determine that a significant

financial interest could directly and significantly affect the design, conduct, or reporting of the research or educational activities funded or proposed for funding; or that the design, conduct or reporting of the research or educational activities could inappropriately benefit the entity in which the investigator has a significant financial interest.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate actual or potential conflicts of interest include, but are not limited to:

1. Public disclosures of significant financial interests;
2. Monitoring of research by independent reviewers;
3. Modification of the research plan;
4. Disqualification from participation in the portion of the funded research that would be affected by the significant financial interests;
5. Divestiture of significant financial interests;
6. Severance of relationships that create conflicts.

If the reviewer(s) determine that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

If an Investigator has a project/activity that has been referred to the CIRC for review of financial conflict of interest, he/she shall not make, participate in making, or use his/her position to influence the making of any decision by the CIRC concerning the conduct of the activity.

- I. The Director of Grants Development will maintain records of all financial disclosures and of all actions taken to resolve actual or potential conflicts of interest until at least 7 years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is longer. The CIRC will maintain records and documentation of all its deliberations, decisions and reports for the same time period.
- J. The Sponsored Programs Director will be responsible for obtaining the financial disclosures that are required after a grant or contract award is made. These will be forwarded to the Grants Development Office for record-keeping purposes, and for referral to the CIRC for review, if necessary.
- K. The Vice President for University Advancement (or designee) will be responsible for obtaining financial disclosures related to gifts for research.

These will be forwarded to the Grants Development Office for record-keeping purposes, and for referral to the CIRC for review, if necessary.

- L. The Director of Grants Development, with the authorization of the Vice President for Academic Affairs, will promptly inform the sponsor in any case in which the University, after CIRC review, has determined that an actual or potential conflict of interest cannot be satisfactorily managed or resolved.
 - M. Failure of an Investigator to make the required disclosure or to disqualify him/herself from CIRC deliberations may result in enforcement proceedings by the sponsor as well as University sanctions.
 - N. Purchases of goods and services on research projects, whether supported through grants, contracts or gifts, are to be made consistent with University policy (or Foundation policy, as appropriate) in which evidence of competitive opportunity is documented.
- II. Composition and Function of the Conflict of Interest in Research Committee

A. Composition

1. The CIRC shall have at least four but no more than seven members appointed by the Vice President for Academic Affairs:
 - a. A faculty or staff person, as appropriate, nominated by the Dean of Research and Graduate Studies;
 - b. An administrator nominated by the Foundation Executive Director;
 - c. A member at large nominated by the Academic Senate;
 - d. A University administrator appointed by the Vice President for Academic Affairs;
 - e. Additional *ad hoc* member(s) as appropriate.

An *ad-hoc* alternate will be chosen by the appointing authority if a member of the CIRC is in the same department or occupational area as the investigator whose financial disclosure is being reviewed.

Individuals from the Grants Development Office or the Sponsored Programs Department shall not participate as members of the CIRC.

2. These members:
 - a. Should be responsible, conscientious persons with impeccable credibility and well versed in the grant/contract and gift processes and regulations of the institution.
 - b. Should have adequate faculty standing or administrative authority and access to subject matter expertise.

- c. May consult with administrators, faculty and others involved in the research review process and the academic discipline in question.
- d. May also consult with Investigators and department chairs in order to gain information and seek modification to the project, if necessary.
- e. Shall maintain records of their deliberations, which shall be made available to the public upon request.

B. Function of the CIRC

1. The purpose of the CIRC is to conduct a substantive review of a research project and the financial disclosure statements of an Investigator, when the Director of the Grants Development Office has referred these to the Committee after consultation with the Dean of Research and Graduate Programs and following guidance provided by the Committee.
2. In making a recommendation to the Vice President for Academic Affairs, the CIRC will consider at least the following:
 - a. Is the activity consistent with the mission and goals of the University?
 - b. Are the teaching and research environments open?
 - c. Is there freedom to publish and disseminate the results of the project?
 - d. Is the use of University facilities appropriate and properly reimbursed?
 - e. Is the nature of the Investigator's financial interest such that a conflict of interest is unlikely to occur and would not compromise the quality and objectivity of the research, including not causing harm to the University or the misuse of state resources?
3. On completion of its deliberations, the CIRC shall file a report with the Vice President for Academic Affairs. At a minimum, the report by the CIRC will consist of:
 - a. Name of Investigator
 - b. Name of project, topic, or activity
 - c. Period of Performance
 - d. Date reviewed by the CIRC
 - e. Funds proposed or awarded
 - f. Documents reviewed by the CIRC
 - g. Nature of financial interest
 - h. Criteria used by CIRC

- i. Assessment of the probability of the financial involvement leading to a conflict of interest, including causing significant harm to either the University or the sponsoring entity.

On the basis of the review, the CIRC will recommend to the Vice President for Academic Affairs, or designee, whether funding for the project should be accepted or continued and, if so, whether any conditions should be imposed.

III. University Action

After considering the report submitted by the CIRC, and consulting with other University officials as appropriate, the Vice President for Academic Affairs, or designee, will determine whether to accept a contract or grant sponsored in whole or in part, or a gift earmarked for the specific Investigator or project. Copies of the disclosure statements, the CIRC's recommendations, and the written decision from the Vice President for Academic Affairs (resulting from the independent review process) are to be provided to the Director of Grants Development, the Sponsored Programs Director in the case of grants/contracts, and the Vice President for University Advancement in the case of gifts. These documents will be available on campus to the public upon request.

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