

CALIFORNIA STATE UNIVERSITY LOS ANGELES

FINANCIAL CONFLICT OF INTEREST POLICY

for

INVESTIGATORS SPONSORED BY THE NATIONAL SCIENCE FOUNDATION (NSF)

AND OTHER NON-PHS GOVERNMENTAL AGENCIES

I. Introduction

This directive provides policies and guidelines regarding disclosure of financial conflict of interest for Principal Investigators for grant and contract funds awarded to the University by the National Science Foundation.

II. Policy

The purpose of this policy is to protect the integrity of research conducted at Cal State LA, as well as the integrity and credibility of researchers associated with the University. This policy is intended to serve as a guide to faculty and other employees with principal responsibility for research projects funded by NSF and to establish procedures to be followed in avoiding and/or resolving actual and potential conflicts of interest pertaining to such projects.

III. Definitions

A. Investigator

Investigator means the project director or principal investigator and any other person, regardless of title or position, who has, or shares, independent responsibility for the design, conduct, or reporting of research funded or proposed for funding by NSF. In this context, "Investigator" also includes the investigator's spouse/domestic partner and dependent children.

B. Outside Activity

Any professional or remunerative activity undertaken by Cal State LA faculty or other professional personnel that is outside the scope of their designated University duties.

C. Financial Interest

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

D. Financial Conflict of Interest

For the purposes of this policy, financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. A conflict exists when it has been determined that:

(a) an outside activity or economic interest undertaken or held by an Investigator (including economic interests of the Investigator's spouse/domestic partner and dependent children) does-

- or appears –to compete, interfere, or otherwise adversely affect the Investigator's professional obligations to the University, Cal State LA UAS and/or a designated external sponsor;

(b) entities in which economic interests are held would be directly and significantly affected by the research or educational activities of the Investigator such that reasonable questions might be raised as to whether such actions are determined primarily by considerations of personal financial gain; or

(c) a significant financial interest could directly and significantly affect the design, conduct or reporting of funded research or educational activities.

E. Institutional Responsibilities

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

F. Required Financial Disclosure

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

G. Significant Financial Interest

Significant financial interests are involved and must be disclosed where one or more of the following financial interests of the investigator (and those of the investigator's spouse/domestic partner or dependent children) reasonably appears to be related to the investigator's Institutional responsibilities:

- A *significant financial interest* exists if an equity interest that, when aggregated for the investigator and the investigator's spouse/domestic partner and dependent children, exceeds \$10,000 in value as determined through reference to public prices or other reasonable measures of market value, and represent more than a 5% ownership interest in any single entity.
- A *significant financial interest* exists when salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse/domestic partner of dependent children, have exceeded or are expected to exceed \$10,000 during any immediately preceding or following 12 month period.

For the National Science Foundation (NSF), a significant financial interest **does not** include:

- Salary, royalties or other remuneration from the applicant Institution;

- Any ownership interest in the Institution, if the Institution is an applicant under the Small Business Innovation Program or Small Business Technology Transfer Program
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- Equity interest and/or salary, royalty and other payments do not exceed the thresholds in the section regarding NSF immediately above.

IV. Disclosure Requirement for Investigators

Each Cal State LA Investigator (as defined above) who submits, renews or participates in a proposal in which NSF funds are sought must file the appropriate financial disclosure statement at the time of the submission of the grant proposal. Such disclosures must be updated at the time of the award (if more than 90 days from initial disclosure) and then on an annual basis during the period of the award and within 30 days of new reportable significant financial interests. New investigators must complete a disclosure before joining an ongoing project.

V. Review and Evaluation of Research Investigator Financial Interest Disclosure Statements

The Investigator will forward completed disclosures to the Office of Research, Scholarship, and Creative Activities (via Cal State LA's UAS) for administrative review. Review will be performed by Associate Vice President for Research or approved designee, and will be based on information provided by the Investigator on the Conflict of Interest Disclosure form, for each entity that may be involved. The AVP for Research or his/her designee, will review disclosures and assess their potential for conflicts of interest. If a disclosure reveals a significant financial interest based on defined criteria and determined to be related to the Investigators' institutional responsibilities, the Investigator will be asked to complete an addendum to the disclosure for use in further evaluation. Copies of the completed disclosure, the addendum, and proposal will then be forwarded to the Associate Vice President for Research.

The Associate Vice President for Research will review the information provided by the Investigator through the disclosure form and addendum statement, evaluate the disclosure to determine whether the financial interest could significantly affect the conduct or reporting of the project, and determine what, if any, conditions or restrictions should be imposed on the Investigator or research protocol in order to manage, reduce or eliminate conflicts that are identified. The Associate Vice President for Research may also evaluate whether the financial interest has the potential to improperly influence financial expenditures, personnel decisions, or facilities usages, or has potential to limit or influence the teaching and research environment of the University. The Associate Vice President for Research may consult with the Investigator, faculty, administrators or other University personnel, as appropriate, in developing a plan to resolve any real or apparent conflict of interest issues.

The Associate Vice President for Research shall report recommendations on all cases considered to the President, Provost, the affected college Dean and Cal State LA's UAS when conditions or

restrictions are implemented to manage the potential conflict. An annual summary report shall also be provided to the Provost and Cal State LA's UAS's Executive Director.

VI. Actions of the Associate Vice President for Research

Acting in a timely manner so as not to unduly delay the conduct of the research, the Associate Vice President for Research shall conclude that the University take one of the following actions: (1) approval of acceptance of the project award; (2) withdrawal of the proposal or disapproval of acceptance of the project award; or (3) approval of acceptance of the project award subject to implementation of recommendations for modifications in either the project proposal or in the external affiliations or economic interests of the Investigator. A management plan with recommended actions to resolve conflicts of interest may include but are not limited to the following:

- Public disclosure of significant financial Interests;
- Monitoring of research by independent reviewers;
- Modification of the research plan subject to sponsor approval;
- Disqualification from participation in the portion of the research that would be affected by the significant financial interests;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts.

VII. Decision and Appeal Process

The conclusions of the Associate Vice President for Research, along with any recommended modifications in the project or the significant financial interests of the Investigator shall be promptly communicated to the Investigator, President, Provost and Cal State LA's UAS's Executive Director. If the Associate Vice President for Research proposes such modifications and the Investigator agrees with the conclusions of the Associate Vice President for Research, the Investigator will provide the Associate Vice President for Research with appropriate documentation sufficient to verify that any such modifications have been made. If the Investigator is dissatisfied with the conclusions of the Associate Vice President for Research, the Investigator may appeal to the President. Acting on behalf of the President, the Provost may investigate and make appropriate recommendations to the President regarding the disposition of the matter. In such cases, the decision of the President shall be final.

VIII. Enforcement Mechanisms and Sanctions

The Office of Research and Sponsored Programs shall withhold access to awards from designated external sponsors when the disclosure statement has not been completed by the Investigator or Associate Vice President for Research or designee. Grants and/or contracts designated for research purposes will not be available to the Investigator until the disclosure has been submitted and reviewed.

Non-compliance with this policy and all matters concerning an Investigator's disclosure of financial interests shall be handled by the Associate Vice President for Research at whose discretion appropriate sanctions or corrective actions may be applied. If the Investigator is dissatisfied with the decision of the Associate Vice President for Research, the Investigator may appeal to the President. Acting on behalf of the President, the Provost may investigate and make appropriate recommendations to the President regarding the disposition of the matter. In such cases, the decision of the President shall be final.

In any cases in which it has been determined that a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this research Investigator conflict of interest policy, the University will require disclosure of the conflicting interest in each public presentation of the results of the research.

IX. Notification of External Sponsor

Initial, annual (i.e. ongoing) and revised FCOI reports must be made to the external sponsor at the following times:

1. Prior to the expenditure of funds;
2. Within 60 days of the identification of an Investigator who is newly participating in the project;
3. Within 60 days for new, or newly identified, FCOIs for existing Investigators;
4. At least annually (at the same time as when the University is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
5. Following a retrospective review to update a previously submitted report, if appropriate.

When identified conflicts of interest are eliminated before research funds are expended, no report need be submitted.

If a Significant Financial Interest (SFI) is identified during the course of an ongoing project that was not previously disclosed or reviewed, the Associate Vice President for Research will review the SFI within sixty (60) days to determine whether it is related to research activities and whether a FCOI exists. If a FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis (see section VI).

If the University determines that a FCOI exists that was not previously identified or managed in a timely manner, the Associate Vice President for Research will complete a retrospective review of the Investigators' activities. This retrospective review must occur (or "be completed") within 120 days of the determination of non-compliance. The purpose of this retrospective review is to determine if the ongoing research activity was biased in its design, conduct or reporting.

Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that the University will take to manage the identified FCOI. If bias was found during the retrospective review, the Associate Vice President for Research will promptly notify the external funding source and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the institution's plans to eliminate or mitigate the effect of the bias.

X. Maintenance of Records

The Office of Research and Sponsored Programs shall maintain records of all disclosure statements and of all actions taken to resolve conflicts of interest for at least three (3) years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained. Copies of all financial disclosures of University employees may also be kept by Human Resources in a manner consistent with other conflict or disclosure statements by University personnel.

XI. Training

There is no training requirement by NSF, but the Institution does provide ongoing training about financial conflicts of interest, and investigators are encouraged to attend.

Contact Information

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