



CALIFORNIA STATE UNIVERSITY, LONG BEACH

OFFICE OF RESEARCH & SPONSORED PROGRAMS

Financial Conflict of Interest Policy

1.0 Purpose

The California State University, Long Beach (CSULB) Financial Conflict of Interest Policy establishes guidelines for the disclosure, identification, and management of financial conflict of interests (FCOI) for Investigators responsible for the design, conduct, or reporting of research under a sponsored research project or when proposing a sponsored project. CSULB Office of Research and Sponsored Programs (ORSP) and the CSULB Research Foundation follow all federal, state, and California State University regulations for reviewing, identifying, and managing FCOI disclosures.

The CSULB ORSP actively encourages involvement of academic researchers and educators with industry and private entrepreneurial ventures. Such involvements, however, can create an increased risk of financial conflict between the private interests of individuals, the entities with which they are involved, and the public interest that governmental funding serves.

This policy is set in place to ensure that Investigators involved in a sponsored research project that is externally funded by contracts or grants from non-governmental sponsors, the National Science Foundation (NSF), or the Public Health Service (PHS), or other agencies adopting federal requirements disclose all significant financial interests (SFI) related to the proposed research. Prior to federal proposal submission CSULB Grants and Contracts Pre-Award Specialists (PAS) review FCOI disclosures to determine if Investigators have potential significant FCOI. Any significant FCOI are further reviewed by the CSULB Director for Research Integrity and Compliance (DRC) and a management plan is implemented to manage, reduce, or eliminate the FCOI. Records of federal financial disclosures and all actions taken to resolve FCOI are maintained for three (3) years beyond the termination or completion of the grant to which they relate or until the resolution of any sponsor action involving those records, whichever is longer. Records of 700U financial disclosures and all actions taken to resolve FCOI are maintained for seven (7) years.

2.0 Responsibility

- CSULB ORSP is responsible for reviewing proposals and awards for FCOI compliance and assuring FCOI compliance.
- CSULB has designated the Associate Vice President for Research and Sponsored Programs (AVP R&SP) as the Institutional Official (IO) who has delegated to the DRC responsibility for reviewing disclosures of SFI of the Investigator (and those of the Investigator's spouse and dependent children as required on the FCOI forms) related to an Investigator's institutional responsibilities.
- CSULB's designated IO is responsible for reviewing FCOI disclosures to ensure that no FCOI exists and that any disclosed SFI is managed, reduced, or eliminated.
- CSULB PAS are responsible for supplying each Investigator with the federal FCOI form. An Investigator must make a financial disclosure using the FCOI disclosure form (for research projects funded by NSF and PHS or other agencies adopting the federal requirements the Investigator completes a Federal

Conflict of Interest Disclosure Form) prior to submitting a proposal for external funding from the NSF, the PHS, federal agencies adopting the federal requirements.

- Each Investigator must complete the FCOI form and submit promptly to CSULB ORSP. Each Investigator must disclose significant financial conflicts of interest before a proposal is submitted, within thirty (30) days of discovering or acquiring a new significant financial interest, and on an annual basis.
- Each Investigator, as designated by the CSU, is responsible for completing mandatory FCOI California state ethics training within six (6) months of receiving a grant. Subsequent training is required at least once within each two calendar year period that the grant is in place.
<http://www.calstate.edu/HRAAdm/pdf2014/HR2014-04.pdf>
<http://www.calstate.edu/gc/Docs/ConflictofInterestHandbook.pdf>
- Each Investigator is responsible for completing mandatory FCOI CITI training prior to engaging in research funded by the PHS. Each PHS funded Investigator must complete CITI refresher training every four (4) years after the initial training, or when the CSULB policy, procedures, or forms are revised in any manner that affects the requirements of Investigators; when new Investigators are appointed to CSULB; and when CSULB ORSP finds that an Investigator is not in compliance with the FCOI regulations or management plan.
- CSULB ORSP is required to make this FCOI policy publicly accessible on a web site or to provide it to any requestor within five (5) business days of a request for the policy.
- Prior to expenditure of any funds under a PHS funded research project CSULB ORSP is required to ensure public accessibility to information concerning disclosures that have been determined to be FCOI related to the PHS funded project.
- CSULB ORSP DRC is responsible for maintaining federal FCOI records for three (3) years beyond the termination or completion of the grant to which they relate or until the resolution of any NSF or PHS action involving those records, whichever is longer. The 700U records are to be maintained for seven (7) years from completion date.

3.0 Policy

3.1 Financial Disclosure

Significant Financial Interest

Investigators are required to disclose SFI whenever an Investigator applies for funding from non-governmental contract or grant sources, the NSF, PHS, or other agencies adopting the federal requirements.

In addition Investigators must disclose SFI annually during the life of a sponsored research project, and within 30 days of discovering or acquiring a new SFI. Significant financial disclosures are defined as follows:

“(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) PHS funded Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Travel disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The CSULB DRC will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by an Investigator’s Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal,

state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.”

Investigator

Investigator is defined as the Principal Investigator (PI) or Project Director (PD), the Co-PI or Co-PD, and any other person, regardless of title or position, who would be responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, including non-CSULB Investigators, consultants, and unpaid collaborators. CSULB DRC is required to consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

Specific Sponsored Program Funders

Sponsored program funders for which FCOI disclosure is required by Investigators before a proposal is submitted or an award is accepted include the following (dependent on the funder):

- National Science Foundation (NSF), Public Health Service (PHS) funds (NIH, FDA, CDC, IHS, HRSA, SAMHSA, AHRQ, ATSDR), including any other agency issuing PHS funds; as well as subcontracts made through another institution for the flow down of NSF or PHS funds; other agencies adopting the federal requirements .
- Private Industry and Private Non-Profit except those excluded from the requirement, as listed on Appendix B of HR2005-38 <http://www.calstate.edu/HRAdm/pdf2005/HR2005-38.pdf> .
- Any government agency that prescribes conflict of interest requirements in a contract or grant.

Forms

An Investigator must make a financial disclosure using a specific FCOI disclosure form.

- For NSF, PHS, or other agencies adopting the federal requirements funded research projects, the Investigator completes a [Federal Financial Conflict of Interest Disclosure Form](#), which can be downloaded from CSULB FCOI webpage: <http://web.csulb.edu/divisions/aa/research/compliance/fcoi/>
- For all nonexempt private sponsors the Investigator completes a [California State Financial Conflict of Interest Form 700U](#), which can be downloaded from CSULB FCOI webpage: <http://web.csulb.edu/divisions/aa/research/compliance/fcoi/>

4. Procedures Overview

4.1 Pre-Award

For all proposal submissions for funding from NSF, PHS, or other agencies adopting the federal requirements, PAS will provide the Federal Conflict of Interest Form and guidelines for completion to each Investigator before proposal submittal. The PAS will include the Federal FCOI disclosure form in the

proposal routing package for review by the Senior Director of Sponsored Programs to ensure the form is complete and for subsequent review by DRC and campus administrators or if subsequent to proposal submittal will forward the Federal FCOI disclosure form to the DRC for review.

Prior to accepting an award from nonexempt private sponsors, the PAS will include the 700U FCOI form in the proposal routing package for review by the Senior Director of Sponsored Programs to ensure the form is complete and for subsequent review by DRC and campus administrators. The DRC will ensure that each Investigator receiving an award from a non-governmental contract or grant sources, or a governmental entity with a contractual conflict of interest requirement complete the 700U FCOI form. Note that the 700U requires that an original (wet) signature be submitted.

When an Investigator discloses a SFI, the applicable CSULB chair, dean, and the AVP R&SP will review the disclosure to determine whether the SFI is related to the sponsored research and whether the SFI is a FCOI. The applicable CSULB chair, dean, and AVP R&SP will work with the Investigator to create a plan of action to mitigate and manage the potential conflict of interest and will provide a copy of the approved mitigation and management plan to the CSULB ORSP PAS for inclusion in an FCOI file within the proposal file.

4.2 Post-Award

Prior to transmitting an award file to the GCA, the PAS will ensure that each Investigator receiving an award for funding from NSF, PHS, other agencies adopting the federal requirements, has an unexpired FCOI disclosure form in place.

Upon award set up the GCA will record the Federal FCOI disclosure form in the PeopleSoft SP Module and indicate the subsequent annual renewal date. Every fiscal year, the DRC will issue annual Federal FCOI disclosure form renewals for all PI's with NSF and PHS funded awards. PI's with NSF and PHS funded awards will have 90 days to complete the Federal FCOI disclosure form renewal. If a PI fails to renew their Federal FCOI disclosure form within the allotted timeframe funding restrictions will be imposed until the renewal form is received.

When an Investigator has disclosed a SFI on a disclosure form, the DRC and assigned GCA will confirm that the form has been countersigned by the AVP R&SP to indicate acknowledgement of the disclosure, and that a copy of an approved FCOI management and mitigation plan accompanies the disclosure form signed by the Investigator and the AVP R&SP, and that a training completion certificate is on file.

Investigators are also required to submit FCOI previously not reported or upon SFI status changes.

4.3 Mandatory FCOI Training

Funded Research Projects (private, nongovernmental entity)

- Each Investigator is responsible for completing mandatory FCOI California state ethics training within six (6) months of receiving a grant. Subsequent training is required at least once within each two (2)

calendar year period that the grant is in place. <http://www.calstate.edu/HRAdm/pdf2014/HR2014-04.pdf> The DRC provides login information to the Investigator for completing this training.

PHS-Funded Research Projects

- Investigators must complete mandatory FCOI CITI training before engaging in research funded by PHS and must also complete refresher training every four (4) years thereafter; when CSULB ORSP or CSULB FCOI policy, procedures, or forms are revised in any manner that affects the requirements of Investigators; when the Investigator is new to a university; and when CSULB or CSULB ORSP finds that an Investigator is not in compliance with the FCOI regulations or management and mitigation plan.

CSULB ORSP DRC provides the CITI FCOI tutorial link to Investigators when research projects are being proposed for PHS-funding. Prior to transmitting an award file to the GCA, the PAS will work with the DRC and the PI to ensure that each Investigator has completed the mandatory FCOI CITI training. Once Investigators complete the mandatory training, the DRC will verify to make sure that the completion records are archived in CITI online system.

4.4 Management of Financial Conflicts of Interest

Prior to the expenditure of awarded funds, the DRC reviews all Investigator disclosures of SFI, determines whether any SFI relate to the funded award, and determines whether a FCOI exists. If a FCOI does exist, the DRC, in consultation with applicable CSULB chair, dean, and the AVP R&SP, will create and implement a management and mitigation plan that shall specify the actions that have been, and shall be, taken to manage such FCOI.

At the discretion of CSULB, examples of conditions or restrictions that might be imposed to manage a FCOI to include, but are not limited to:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of FCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or severance of relationships that create FCOI; and
- Upon implementation of the management plan, CSULB shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the funded award.

4.5 Reporting Financial Conflicts of Interest to PHS

CSULB ORSP DRC will submit a report to NIH or other PHS-funded agency regarding any Investigator SFI found by the Institution to be a FCOI in accordance with the regulation prior to expenditure of any funds under a PHS-funded research project. CSULB ORSP will also provide an FCOI report whenever an Investigator does not timely disclose a SFI or whenever CSULB ORSP, for whatever reason, does not review a disclosed SFI and the Institution then determines that a FCOI exists.

CSULB ORSP will submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new SFI to the Institution during the period of award. CSULB ORSP will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI going forward and submit an FCOI report to the NIH or other PHS-funded agency.

CSULB ORSP will also, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's research activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct or reporting of such research. Based on the results of the retrospective review, if appropriate, CSULB ORSP will update the previously submitted FCOI report; specify the actions that will be taken to manage the FCOI going forward. If bias is found, CSULB ORSP will notify the funding agency promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

Thereafter CSULB ORSP will submit FCOI reports to the PHS-funded agency annually for any FCOI previously reported. The annual FCOI report shall address the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why it no longer exists. Annual FCOI reports will be submitted to the funder (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when the Institution is required to submit the annual progress report (i.e., two (2) months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable), but is not to be submitted as part of the annual progress report.

The annual FCOI report will be submitted to PHS-funded agency separately through the eRA Commons FCOI Module and will include the following key elements:

- (A) The role and principal duties of the conflicted Investigator in the research project;
- (B) Conditions of the management plan;

- (C) How the management plan is designed to safeguard objectivity in the research project;
- (D) Confirmation of the Investigator's agreement to the management plan;
- (E) How the management plan will be monitored to ensure Investigator compliance; and
- (F) Other information as needed.

CSULB ORSP follows all federal, state, and California State University regulations for reviewing SFIs and for identifying, managing, reducing, eliminating, and reporting FCOIs.

4.6 Enforcement Mechanisms and Remedies for Non-Compliance for PHS-funded

As required by PHS regulations, CSULB ORSP will notify the sponsoring agency promptly of the corrective action taken or to be taken for non-compliance by an Investigator and the non-compliance appears to have biased the design, conduct, or reporting of the PHS-funded research. PHS FCOI regulations will be followed for the conduct of retrospective reviews and management and mitigation reports.

As required by PHS regulations, CSULB ORSP will require the Investigator(s) to disclose an FCOI in each public presentation of the research results and to request an addendum to previously published presentations for any clinical research projects supported by the PHS, should the Department of Health and Human Services determine that the PHS-funded project of clinical research, whose purpose is to evaluate that safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed.

CSULB ORSP will complete and document retrospective reviews within 120 days of a determination of non-compliance for SFI not disclosed timely by the Investigator, not initially identified when previously reviewed, or whenever an FCOI is not identified or managed in a timely manner, and will document the reviews as required by the regulation.

4.7 Subrecipient Requirements

Prior to including a subrecipient in a PHS-funded research proposal, the CSULB ORSP Senior Director of Sponsored Programs will confirm, through use of the written subrecipient information form, that all proposed subrecipients have a FCOI interest policy that complies with FCOI regulations and that the subrecipient will report identified FCOIs for its Investigators in a timeframe that allows CSULB ORSP to report identified FCOIs as required by the regulation.

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

CSULB ORSP will report to the PHS-funding agency any FCOI that is identified by any subrecipient, subcontractor, collaborator, or consultant in the manner required under FCOI regulations prior to expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

5.0 Required Forms

These are the referenced and required forms of the Financial Conflict of Interest Policy.

Form	Description of Use
Form 700U	Must be completed (wet signature required) by Investigator for financial disclosure prior to receiving sponsored funding from a non-governmental entity.
Federal Conflict of Interest Disclosure Form (federal)	Must be completed by Investigator for financial disclosure when Investigator prior to submitting for sponsored funding from a government agency that requires disclosure of Significant Financial Interests such as NSF and PHS-funded research.
Subrecipient Information Form	Must be completed by potential subrecipients or subcontractors to provide contact and regulatory compliance information and disclosures.

6.0 Record Retention

All documents and records are maintained in accordance with the CSULB ORSP Record Retention Policy.

Record	Retention
Federal FCOI disclosure form and all documents related to the management of an FCOI	Three years
Form 700U	Seven years

7.0 Definitions

Refer to the following table for definitions as used in Conflict of Interest Policy.

Term or Acronym/Abbreviation	Description
Financial Conflict of Interest	A Financial Conflict of Interest (FCOI) exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to an NSF-, PHS-, or other funded research project and could directly and significantly affect the design, conduct, or reporting of the NSF-, PHS- or other- funded research.
Institutional Responsibilities	Institutional responsibilities are defined by the 2011 revised PHS regulation as an Investigator's professional responsibilities on behalf of the Institution, and as defined by the institution in FCOI policy, 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.

Investigator	In this policy investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by NSF, PHS, or other agencies adopting the federal requirements, or proposed for such funding, which may include, for example, collaborators or consultants. For sponsored projects funded by non-governmental agencies or government agencies with contractual conflict of interest clauses the institution officials may determine that investigators are limited to the PI or Co-PIs of the sponsored program.
Significant Financial Interest	Interest that would create a conflict of interest is defined as any financial interest that a principal investigator would have that would reasonably appear to be directly and significantly affected by sponsored activities or any interest that a principal investigator would have in entities whose financial interest would reasonably appear to be directly and significantly affected by sponsored activities.
Sponsored Travel	Travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available.

8.0 References and Related Policy Information

42 CFR Part 50, 45 CFR Part 94 http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

NIH FCOI <http://grants.nih.gov/grants/policy/coi/index.htm>

NIH FCOI FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

NSF FCOI <http://www.nsf.gov/policies/conflicts.jsp>

CSU HR 2014-04 <http://www.calstate.edu/HRAdm/pdf2014/HR2014-04.pdf>

CSU COI Handbook <http://www.calstate.edu/gc/Docs/ConflictofInterestHandbook.pdf>

California Fair Political Practices Commission <http://www.fppc.ca.gov>