

510-000-A: Financial Conflict of Interest Policy for Government Funding

This policy supplements California State University systemwide policy: [Financial Conflict of Interest for Investigators](#) (ICSUAM 11010.02) and further with certain federal regulations governing financial conflicts of interest.

I. Purpose

The University Corporation at Monterey Bay (the “University Corporation”) Financial Conflict of Interest Policy-Government Funding 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 from government agencies requiring FCOI compliance.

The University Corporation at Monterey Bay on behalf of California State University, Monterey Bay 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. The University Corporation recognizes that these conflicts may arise due to interests and investments that faculty and families may have. The existence of a significant financial interest and any resulting financial conflict(s) is not prohibited in and of itself, but such conflicts must be disclosed to the University Corporation and managed appropriately.

II. Policy

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 government sponsors, the National Science Foundation, or the Public Health Service (including other agencies obliged to comply with the requirements) disclose all significant financial interests (SFI) related to the proposed research as required by the regulations. This policy applies to awards received directly from the designated sponsors or as a pass-thru award.

III. Definitions

- A. *Family*: Any member of the Investigator’s immediate family, specifically, any dependent children, spouse or domestic partner.
- B. *Financial Conflict of Interest*: A Financial Conflict of Interest (FCOI) exists when the University Corporation, through its Institution Official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to an NSF, PHS, or other government funded (that requires FCOI compliance) research project and could directly and significantly affect the design, conduct, or reporting of the NSF, PHS or other government funded research.

Financial Interest: Anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests. For PHS Investigators, *Financial Interest* also includes *Sponsored Travel* (as defined below).

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;

- b) income from the authorship of academic or scholarly works;
 - c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
 - d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
- C. *Institutional Official (IO)*: The individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the IO is designated as the University Corporation Compliance Officer
- D. *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.
- E. *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 proposed for such funding, which may include, for example, collaborators or consultants. For sponsored projects funded 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.
- F. *National Science Foundation (NSF)*: A federal government agency that supports fundamental research and education in all the non-medical fields of science and engineering.
- G. *Public Health Service (PHS)*: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration. Other agencies may also adopt the PHS FCOI regulations.
- H. *Related Entity*: Means any domestic or foreign, public or private, for profit, non-profit or governmental organization in which the Investigator, alone or in combination with his or her Family, holds a Significant Financial Interest.
- I. *Remuneration*: Includes salary and payments for services, such as consulting fees, honoraria or paid authorship, and cash or in-kind gifts from entities for which you provide services and, for PHS Investigators-Sponsored Travel
- J. *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 and;

- i. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- ii. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- iii. if with a non-publicly traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- iv. is income related to intellectual property rights and interests not reimbursed through the Institution.

K. *Sponsored Travel*: For PHS Investigators only, Sponsored Travel includes (a) travel expenses paid to an Investigator or travel paid on an Investigator's behalf, by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigator's Family by a single entity in any 12-month period and equals or exceeds \$5,000, alone or in combination with other remuneration and equity interests related to Institutional Responsibilities. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

IV. Disclosure of Financial Interests

All Investigators are required to disclose their outside financial interests to the Institution at the time of application for PHS or NSF funded research, on an annual and on an *ad hoc* basis, as described below. The IO, or designee (including the Sponsored Programs Office), is responsible for the distribution, receipt, processing, review and retention of disclosure forms. Other government agencies requiring FCOI compliance shall complete reporting as required by the funding agency.

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

A. Proposal Disclosure

All Investigators must disclose their Significant Financial Interests to the Institution, at the time of application for NSF, agencies following PHS funding FCOI regulations or other governmental funding with FCOI requirements.

B. Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution, at least annually while supported by PHS, NSF funding or other governmental funding with FCOI requirements.

C. Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure:

- i. New Investigators must complete an initial disclosure of SFIs before joining an ongoing PHS or NSF funded award.
- ii. All Investigators with PHS or NSF funded research must submit to the IO an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

Travel

PHS requires that Sponsored Travel be included in the determination of whether the Aggregate value of an Investigator's financial interests rises to the level of a Significant Financial Interest. Sponsored Travel includes (a) travel expenses paid to an Investigator or travel paid on an Investigator's behalf, by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigator's Family by a single entity in any 12-month period if such travel reasonably appears to be related to the Investigator's Institutional Responsibilities.

Looking back over the previous twelve-month period provides baseline information that allows the University Corporation to consider whether Investigators have an ongoing financial relationship with an entity providing a payment or reimbursement or whether the payment or reimbursement was limited in duration.

In order to ensure compliance with PHS regulations, therefore, an Investigator must update FCOI disclosure to include Sponsored Travel if the Sponsored Travel equals or exceeds \$5,000, alone or in combination with other Remuneration and Equity Interests:

- at the time of submission of a proposal to PHS, looking back over the previous 12 months;
- thereafter, within 30 days following reimbursement or within 30 days following the completion of a trip, if the PHS Investigator has an active award or pending proposal with a PHS agency.

An Investigator need not disclose Sponsored Travel paid for or reimbursed by:

- CSUMB/University Corporation (e.g. paid from CSUMB/University Corporation funds or from sponsored awards managed at CSUMB/University Corporation)
- U.S. Federal, state or local governmental agencies
- U.S. Institutes of higher education
- U.S. Research institutions affiliated with institutions of higher education
- U.S. Academic teaching hospitals and medical centers

The disclosure must include at a minimum, the purpose, the identity of the organization or entity funding the travel, the destination, and the duration of the trip. The IO will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's PHS funded research.

V. Management of Financial Conflicts of Interest

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the IO for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the IO will take action to eliminate, reduce, or manage the conflict, as appropriate.

A Financial Conflict of Interest will exist when the IO determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the supported research. If the IO determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related supported research goes forward. The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the IO.

To address complex situations, an oversight committee may be established on an ad hoc basis by the IO to assist in the creation and/or review of the management plan, and/or periodically review the ongoing activity, and/or monitor the conduct of the activity (including use of students and postdoctoral appointees), and/or ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest 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 financial conflict of interest;
- Modification of the research plan;
- 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 financial conflicts.

Upon implementation of the management plan, the IO shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the funded award.

VI. PHS Mandatory FCOI Training

Investigators must complete mandatory FCOI training before engaging in research funded by Public Health Service (PHS) and every four (4) years thereafter. In addition, Investigators will be informed when any of the following applies: 1) the FCOI Policy-Government Funding, the Disclosure Form or the FCOI procedures are revised in any manner that affects the requirements of the Investigators; 2) an Investigator is newly appointed to a university; 3) the University Corporation finds that an Investigator is not in compliance with the FCOI regulations or management plan.

Sponsored Programs Office provides the Collaborative Institutional Training Initiative (CITI) mandatory online training delivery for PHS FCOI: <https://csumb.edu/compliance/coi-training>

VII. PHS Reporting, Enforcement and Remedies

A. Reporting Financial Conflicts of Interest to PHS

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

The IO 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 Significant Financial Interest to the Institution during the period of award. The IO 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 Financial Conflict of Interest going forward and submit an FCOI report to the NIH or other PHS-funded agency.

The IO will also, within 120 days of the determination of noncompliance, 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 noncompliance, was biased in the design, conduct or reporting of such research. Based on the results of the retrospective review, if appropriate, the IO will update the previously submitted FCOI report; specify the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the IO will notify the NIH 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, the IO will submit FCOI Reports to NIH or other PHS-funded agency annually for any Financial Conflict of Interest 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 Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. Annual FCOI reports will be submitted to the NIH (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 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 NIH separately through the eRA Commons FCOI Module and will include the following key elements:

- i. The role and principal duties of the conflicted Investigator in the research project;
- ii. Conditions of the management plan;
- iii. How the management plan is designed to safeguard objectivity in the research project;
- iv. Confirmation of the Investigator's agreement to the management plan;
- v. How the management plan will be monitored to ensure Investigator compliance; and
- vi. Other information as needed.

B. Enforcement Mechanisms and Remedies for Non-Compliance for PHS-funded Sponsored Research

As required by PHS regulations, the IO will notify the sponsoring agency promptly of the corrective action taken or to be taken for non-compliance by an Investigator and the noncompliance 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, the IO 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.

The IO will complete and document retrospective reviews within 120 days of a determination of noncompliance for SFIs 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.

VIII. Investigator Non-Compliance

Substantive violations of this policy, such as instances of falsification or willful concealment of Significant Financial Interests, or failure to implement or maintain necessary modifications as required by the IO and agreed to by the investigator, may constitute violations of CSUMB's Research Misconduct Policy. The Research Misconduct Policy and corresponding Procedures will be followed.

IX. PHS Public Disclosure

The University Corporation is required to make this FCOI policy publicly accessible on a web site or to provide it to any requestor within five business days of a request for the policy.

As also required by PHS, any disclosed significant financial interest(s) of investigators as defined in this policy, and any resulting management plan(s) will be made publicly available within five (5) days of a lawful request for such information. General public disclosure laws and regulations may require disclosure of other conflict of interest documents and findings.

X. Subrecipient Requirements

Prior to including a subrecipient in a NSF or PHS-funded proposal, the Sponsored Programs Office will confirm, through use of the written subrecipient commitment form, that all proposed subrecipients have a FCOI interest policy that complies with applicable FCOI regulations and that the subrecipient will report identified FCOIs for its investigators in a timeframe that allows the University Corporation to report identified FCOIs as required by the regulations. A subaward shall not be issued without the subrecipient's compliance with the applicable FCOI regulations.

The University Corporation Compliance Officer IO will report to the PHS-funding agency any FCOI that is identified by any subrecipient, subcontractor or collaborator, in the manner required under FCOI regulations prior

to expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

XI. Required Forms

These are the referenced and required forms of the Financial Conflict of Interest Policy-Government Funding per section 4.00.

- Financial Conflict of Interest Form – 1
- Financial Conflict of Interest Form – 2
- Subrecipient Commitment Form

XII. Record Retention

Records of financial disclosures and all actions to resolve conflicts of interest are maintained for three years from the date of the final expenditure report submitted to the agency or until the resolution of any sponsor action involving those records, whichever is longer.

The information provided herein may be released or transmitted to the sponsor, including federal agency representatives, and according to the California Public Records Act, may also be released to the public, upon request.

Where there are substantive differences between the policy and the referenced or related documents below, the regulations shall take precedence.

XIII. Adoption and Review

- A. The University Corporation's Board of Directors has adopted this Conflict of Interest for Government Funding Policy, dated June 2016.
- B. The policy shall be evaluated ten years from its adoption date to determine its effectiveness and appropriateness. The policy may be evaluated before that time as necessary to reflect substantial organizational, financial, or physical change(s) at the University Corporation or any change required by law or by other governing policy.

Any proposed amendments or variations of this policy would require a majority approval by the University Corporation Board of Directors.

XIV. Related Documents

- A. 42 CFR Part 50, 45 CFR Part 94 http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- B. NIH FCOI <http://grants.nih.gov/grants/policy/coi/index.htm>
- C. NIH FCOI FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- D. NSF FCOI http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/aag_4.jsp#IVA
- E. CSUMB Research Misconduct Policy <https://csumb.edu/policy/research-misconduct-policy>
- F. 510-002-A: Non-Government COI Procedure
- G. 510-002-B: Government FCOI Procedure
- H. Financial Conflict of Interest Form – 1
- I. Financial Conflict of Interest Form – 2
- J. Subrecipient Commitment Form