

CSUSM Corporation Office of Sponsored Projects Conflict of Interest Procedure

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Introduction: This document outlines state and federal requirements for investigator disclosure of financial conflicts of interest for those who seek and obtain external funding from a non-governmental entity or from the National Science Foundation (NSF) or Public Health Services (PHS) or other federal agency requiring financial conflict of interest disclosure. The State of California requires principal investigators to disclose financial interests with non-governmental entities from which funding is requested to ensure public employees are not personally benefitting at the expense of the public interest. The NSF and PHS require investigators to disclose all financial interests that could potentially bias research outcomes. There are several other federal and non-federal funding agencies that have adopted the PHS policy on financial conflicts of interest. The Office of Graduate Studies and Research is responsible for collecting initial COI forms prior to submitting proposals. The Office of Sponsored Projects is responsible for renewals, as required, for awards accepted and managed by the CSUSM Corporation.

Purpose: The purpose of this procedure is to comply with state and federal requirements regarding financial conflicts of interest.

Private, Non-Governmental Funding Procedure

I. Financial Conflicts of Interest Requirements

The purpose for conflict of interest laws is to prohibit public employees from personally benefitting at the expense of the public interest. The Political Reform Act of 1974, administered by the Fair Political Practices Commission (FPPC), is often regarded as the principal conflict of interest law, and is the guiding regulation for the CSU Conflict of Interest Code (see CSU Conflict of Interest Handbook) and the Integrated CSU Administrative Manual (ICSUAM) Policy 11010.02. The ICSUAM defines a Significant Financial Interest as “anything of monetary value, including but not limited to salary or other payments for service (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options); being an owner, partner, director or officer in a non-publicly held company or entity; and, intellectual property rights (e.g., patents, copyrights) and royalties from such rights.”

This procedure applies to Principal Investigators (PI) and requires they disclose any financial interests they have as a principal investigator, or their spouse/domestic partner and dependent children, may have with a non-governmental funding entity.

Information requested on all FPPC forms is used by the FPPC to administer and enforce the Political Reform Act. Failure to provide all the information required by the Act is a violation subject to administrative, criminal or civil prosecution. All reports and statements provided are public records open for public inspection and reproduction.

Referenced regulations, code, and policy:

1. The FPPC regulation pertaining to PIs can be found in Title 2, Division 6, Section 18755:
<http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/LegalDiv/Regulations/Index/Chapter7/Article3/18755.pdf>
2. CSU Conflict of Interest Handbook (COI code): <https://www2.calstate.edu/csusystem/faculty-staff/systemwide-human-resources/conflict-of-interest>
3. ICSUAM Policy 11010.02 (Sponsored Projects Administration):
<http://www.calstate.edu/icsuam/sections.shtml>

A. Exempt Private Agencies

Research funding by certain nonprofit entities will not trigger disclosure. Exempt sponsors are listed in Title 2, Division 6, Section 18755 of the FPPC regulation.

B. Disclosure, Training, Review, and Management

1. The [700-U Statement of Economic Interests for Principal Investigators form](#) is required by all persons employed by the CSU who have principle responsibility for a research project if the project is to be funded or supported, in whole or in part, by a contract or grant (or other funds earmarked by the donor for a specific research project or for a specific researcher) from a nongovernmental agency.

Disclosure is required prior to final acceptance of a contract or grant, or within 30 days after funding is renewed. OGSR Grants and Contracts Development will collect the completed 700-U disclosure forms during the proposal stage prior to submitting proposals. In the event of an award, CSUSM Corporation Office of Sponsored Projects will then maintain ownership of the completed forms and oversee their renewal.

2. Training Requirements

In accordance with the Fair Political Practices Commission requirements and consistent with ICSUAM, Principal Investigators must complete the CSU Ethics and Conflict of Interest training within six (6) months of receiving an award. Subsequent training is required as least once each consecutive period of two calendar years that the grant is in place. To ensure training is completed, Grants and Contracts Development will require training certificates prior to sharing the proposal records with the Office of Sponsored Projects for award set-up.

To gain access to the CSU Ethics and Conflict of Interest training, Grants and Contracts Development must provide the Investigator's name and email address to the campus filing officer or designee in the CSUSM Office of Human Resources (HR). In coordination with Grants and Contracts Development and HR, the Investigator will receive an email notification when they have been granted access to the training module.

3. Review of Disclosed Conflicts

If a financial interest is disclosed on the 700-U form, the Grants and Contracts Specialist or Administrative Coordinator on the Grants and Contracts Development team will share the form with the Dean of Graduate Studies and Research and Director of the Office of Sponsored Projects and they will determine whether the disclosure meets the definition of significant financial interest (SFI). If a significant financial interest or the appearance of a significant financial interest is determined, the disclosure form will be shared with the Conflict of Interest Review Committee to make recommendations for the management of the conflict(s) as necessary. The CIRC consists of the following: two faculty selected in consultation with Academic Senate, one administrator from CSUSM Corporation, Dean of Graduate Studies and Research, and VPFAS or designee.

4. Management of FCOIs

Management of financial interests will be set by the ad hoc independent review committee. Some examples of management are:

- Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others;
- Abstention from certain project segments or decisions;
- Modification of the external commitment or financial interest;
- Modification of the research plan (including the assignment of responsibilities);
- Divestiture or severance of an external commitment or financial interest

Federal Funding Procedure

II. Financial Conflicts of Interest Requirements

Federal policy requires CSUSM researchers and investigators submitting to NSF, PHS agencies, or agencies who have adopted the PHS policy to disclose any significant financial interest, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding. The review and management of significant financial interests promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from conflicts of interest.

A. Definitions

1. Investigator

The principal investigator or project director, co-principal investigator, and any other personnel who would be responsible for the design, conduct, or reporting of research or educational activities funded by the PHS/NSF or proposed for such funding, which may include, for example, consultants, investigators on subawards, and unpaid collaborators. *For purposes of this policy, regardless of funding source, "Investigator" also includes the investigator's spouse/domestic partner and dependent children.*

2. Disclosure

Disclosure is the process of a CSUSM investigator, as defined above, completing and submitting a Financial Conflict of Interests form to the Office of Graduate Studies and Research (during the proposal stage) or Office of Sponsored Projects (during the period of the award) when the following occur:

Public Health Services (PHS) disclosures:

- Initial proposal (prior to submission) – collected by OGSR Grants and Contracts Development
- Non-competing continuations – collected by the Office of Sponsored Projects
- Renewals – collected by OGSR Grants and Contracts Development
- Supplemental funding – collected by OGSR Grants and Contracts Development
- New personnel added must be reported within 60 days of addition – collected by the Office of Sponsored Projects
- New financial interests that would be considered "significant" according to PHS must be reported within 30 days of acquiring or discovering new significant financial interests – collected by the Office of Sponsored Projects

National Science Foundation (NSF) disclosures:

- Initial proposal (prior to submission) – collected by OGSR Grants and Contracts Development
- New personnel added – collected by the Office of Sponsored Projects
- Any change in an investigator's financial interest – collected by the Office of Sponsored Projects

3. Significant Financial Interest

Public Health Services (PHS)

A Significant Financial Interest (SFI) related to the investigator's institutional responsibilities including:

- If publicly traded entity, total value of compensation and equity interest > \$5,000
- In non-publicly traded entity, total value of compensation > \$5,000 or any equity interest
- Income received related to intellectual property >\$5,000
- Any reimbursed or sponsored travel *Excluding (1) travel that is reimbursed or sponsored by a state or government agency, university, teaching hospital, medical center, or research institute affiliated with a university; or (2) travel for the investigator's spouse/domestic partner and/or dependent children.

PHS disclosure requirements: https://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

National Science Foundation (NSF)

A SFI related to the research project including:

- Income >\$10,000
- Equity (of any type) >\$10,000 or 5%
- Director, Officer, Employee, Partner, Trustee, Consultant or Management position
- Intellectual Property

NSF disclosure requirements: https://www.nsf.gov/pubs/policydocs/pappguide/nsf09_29/aag_4.jsp

4. Financial Conflict of Interest (FCOI)

A FCOI is a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the funded research.

The following are examples of when an Investigator would be deemed to have a financial conflict of interest:

(i) if the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed PHS/NSF-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application, or

(ii) the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from the University which has resulted in license income and that technology is the subject of a proposed PHS/NSF-funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.

5. Designated Institutional Officials

The Dean of Graduate Studies and Research and the Director of the Office of Sponsored Projects are the designated officials for the review and identification of financial conflicts of interest.

B. Training Requirement

Grants and Contracts Development shall be responsible for ensuring that each investigator is informed about (i) the PHS and NSF financial conflict of interest policies, (ii) the investigator's responsibilities regarding disclosure of Significant Financial Interests, and (iii) the CSUSM Corporation FCOI Procedures in the proposal stage prior to an award. Grants and Contracts Development and the Office Sponsored Projects (which office depends on timing) shall require each investigator to complete training:

1. Prior to engaging in research related to any PHS funded grant, cooperative agreement or contract (Grants and Contracts Development will require initial training);
2. At least every four (4) years thereafter (Office of Sponsored Projects will require training during award); or
3. Immediately (within 10 business days following the event that triggers the training requirement) when any of the following applies:
 - a) CSUSM Corporation revises this procedure that affects requirements of Investigators,
 - b) An Investigator is newly appointed at the University and transfers their PHS funding, to CSUSM; or
 - c) An Investigator is newly appointed to a PHS funded research grant as the PI or key personnel; or
 - d) CSUSM Corporation finds that an Investigator is not in compliance with this Policy or their management plan.

The PHS Conflict of Interest course can be accessed on our Collaborative Institutional Training Initiative (CITI) site:

1. Link: <https://www.citiprogram.org/>
2. Click *Register* under *Create an Account*
3. Create a profile with California State University, San Marcos
4. Under *Add a course*, Proceed to Question 1, Select COI in Question 8.

The Grants and Contracts Development team will notify the PI and senior personnel of training requirements when a PHS award is received. Grants and Contracts Development will require training certificates prior to sharing proposal records with the Office of Sponsored Projects for award set-up. In the event PHS training is not completed at the time of award, Grants and Contracts Development will notify the Office of Sponsored Projects so that a project account is not established until the required training is completed. See the Office of Graduate Studies and Research website for a CITI registration guide: <https://www.csusm.edu/gsr/irb/training.html>.

C. Disclosure, Review and Management Requirements

1. Making a Disclosure

Disclosures occur through the action of an investigator completing and submitting a CSUSM Corporation Financial Disclosure Form as a component of the proposal submission. These forms can be located on the CSUSM Corporation Conflict of Interest website.

a) Disclosures must be submitted when seeking PHS funding (or funding from other agencies that have adopted the PHS policy) in accordance with the following milestones:

- No later than at the time of application for funding; (collected by Grants and Contracts Development)
- At least annually during the period of the award (collected by Office of Sponsored Projects);
- Within 30 days of discovering or acquiring a new SFI (collected by Office of Sponsored Projects);
- Within 60 days of the addition of an Investigator new to participating in the research project (collected by Office of Sponsored Projects) or transferring a project to CSUSM from another institution (collected by Grants and Contracts Development).

b) Disclosures must be submitted when seeking NSF funding in accordance with the following milestones:

- No later than at the time of application for funding (collected by Grants and Contracts Development);
- Or as new reportable significant financial interests are obtained (collected by Office of Sponsored Projects).

If a new SFI is disclosed prior to an annual deadline, the deadline will be extended to a year from the most recent disclosure.

Outstanding FCOI forms may cause a delay in the set up of a new project account or an account hold being placed on the respective projects until outstanding disclosures are completed and received at the initial proposal or annual renewal stage.

2. Review of Disclosures

Identified conflicts of interest are reviewed prior to expenditure of funds by the Dean of Graduate Studies and Research or the Director of Sponsored Projects to determine whether an Investigator has a Significant Financial Interest (SFI) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definitions of SFI.

Identified SFI results in further disclosure to the Conflict of Interest Review Committee (CIRC) to reasonably determine whether the SFI is a Financial Conflict of Interest (FCOI) that could directly and significantly affect the design, conduct, or reporting of the funded research.

Following the determination of an FCOI, the CIRC shall make a final determination involving one of the following administrative actions:

1. Accepting the sponsored project award subject to suitable modification in the award documentation or in the investigator's, or his/her family's, affiliation with the external constituencies involved. Possible modifications are explained below in Management of FCOI;
2. Implement a management plan within sixty days whenever an SFI is identified that was not disclosed timely by the Investigator or not previously reviewed by the campus; or
3. Not accepting the sponsored project award.

3. Management of FCOI

Management plans developed to mitigate FCOIs will be overseen by the designated institutional officials. Grants and Contracts Development and the Office of Sponsored Projects, in conjunction with the investigator(s), the College Dean, Department Chair, and the Provost, will finalize the management plan and communicate it to the affected research personnel. Management measures may include, as appropriate, but are not limited to:

- Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others;
- Research personnel's abstention from certain project segments or decisions;
- Modification of the external commitment or financial interest;
- Modification of the research plan (including the assignment of responsibilities);
- Monitoring of the potentially affected research activity by an independent individual or subcommittee;
- Divestiture or severance of an external commitment or financial interest;
- Independent review of student research progress;
- Discontinuation of advisee's or subordinate employee's participation in external entity.

The management plan will state who is responsible for overseeing the implementation of the plan, and for reporting compliance at pre-determined intervals until the completion of the project. If the management plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made.

4. Appeals to FCOI Determinations

Appeals to a positive finding of a FCOI determination that results in declination of the sponsored project award, or a FCOI determination that results in the implementation of a management plan can be made to the Provost for final review, discussion, and determination. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award.

In reviewing positive findings that are appealed, the Provost will be guided by the following principles:

1. Assure adherence to all relevant CSUSM policies and provisions of collective bargaining agreements;
2. Give full consideration to the nature and extent of the financial interests in the relationship of the investigator, and/or the investigator's family members, with the external constituencies;
3. Give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation; and
4. Consult fully with the investigator and obtain additional information from the investigator, as deemed appropriate to the management of the apparent FCOI.

D. Reporting Financial Conflicts of Interests

1. NIH Reporting Requirements

Reports will be sent to NIH during the circumstances and deadlines specified below:

- When the designated institutional officials have discovered an initial SFI and implemented a management plan, reporting will be completed prior to the expenditure of funds;
- Within 60 days of identification of SFI for an Investigator who is newly participating in the project;
- Within 60 days for new, or newly identified, SFIs for existing Investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, or at time of extension) to provide the status of the SFI and any changes to the management plan, if applicable, until the completion of the project;
- Following a retrospective review to update a previously submitted report, if appropriate;
- Promptly upon discovery of bias with the design, conduct or reporting of NIH-funded research with a mitigation report in accordance with the regulation;
- Promptly upon discovery of an Investigator failing to comply with the Institution's FCOI policy or if a FCOI management plan appears to have biased the design, conducts, or reporting of the NIH-funded research.
 - A management plan will be implemented and reported within sixty days of discovering a failure to comply.

2. NSF Reporting Requirements

In the event of discovering an FCOI that cannot be satisfactorily managed, either by the Investigator, the Office of Sponsored Projects, the Office of Graduate Studies and Research, or the Institution, the Director of Sponsored Projects will keep the NSF's Office of the General Counsel appropriately informed of the situation and seek assistance.

E. Subrecipient Compliance and Reporting

All proposed subrecipients under PHS/NSF funded research of the University shall have a financial conflict of interest policy that conforms to the requirements of the PHS and NSF financial conflict of interest regulations, or certify to follow CSUSM Corporation's FCOI policy and procedure. If the subrecipient individual(s) have an identified FCOI, it should be revealed, by their employing institution, to CSUSM Grants and Contracts Development before proposal submission.

If the subrecipient individuals will be following the CSUSM Corporation procedure, they will be required to disclose their Significant Financial Interests directly to Grants and Contracts Development. If it is determined that there is an FCOI, they will be subject to the same requirements as are CSUSM-employed investigators.

CSUSM will report to the NIH funding agency any FCOI in accordance with Section D. of this procedure.

F. Remedies and Noncompliance

If an Investigator fails to comply with this FCOI procedure or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS/NSF funded research, CSUSM Corporation as required under federal regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, CSUSM Corporation shall ensure compliance with the requirements for retrospective review, to be completed within 120 days of identification, and prepare a mitigation report, if needed, for submission to the applicable funding agency. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the University to take further action to maintain the objectivity of the research.

For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the 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 as required under 42 CFR 50, the University, through the Office of Graduate Studies and Research, must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

G. Enforcement and Sanctions

All persons subject to this FCOI procedure are expected to comply with it fully and promptly. Whenever an Investigator has violated the CSUSM COI policy, for example by a failure to disclose a Significant Financial Interest, the designated officials may refer the matter to the appropriate university official or committee for disciplinary action or other appropriate action.

Violations of this procedure and the PHS/NSF Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the respective university policy and procedures governing allegations of research misconduct. See [Misconduct in Scholarship and Research](#) policy.

In addition, with respect to conflicts of interest that are not properly disclosed and handled, State of California ethics laws may apply. Violations of the State ethics laws can lead to civil fines and criminal prosecution.

H. Records

CSUSM Corporation is required to maintain all disclosures and all related records of actions taken by the university with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS/NSF or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

I. Federal sponsors that have adopted PHS regulations

This list of agencies adopting PHS requirements may be found on the FDP Institutional Clearinghouse website: <http://thefdp.org/default/fcoi-clearinghouse/fcoi-agencies/>.

J. Roles and Responsibilities

Office of Sponsored Projects: The Office of Sponsored Projects is responsible for oversight of FCOI compliance of active projects as described in this procedure.

Office of Graduate Studies and Research, Grants and Contracts Development: The Office of Graduate Studies and Research Grants and Contracts Development Team is responsible for compliance with proposal stage FCOI compliance and ensures disclosure forms and training certificates are complete prior to award set-up.