



SPONSORED PROJECTS CONFLICT OF INTEREST POLICY

PURPOSE:

To comply with the California Code of Regulations (2 CCR § 18755); the Code of Federal Regulations (2 CFR 200.112); the policies of the National Science Foundation (NSF); and the policies of the Public Health Service agencies (e.g., NIH, HRSA, FDA, CDC, SAMHSA, AHRQ, Indian Health Service and ATSDR).

POLICY:

I. Basic Requirements

State and Federal regulations require all persons with a significant role in the project to disclose whether or not he/she has a direct or indirect financial interest in the sponsor or agency. Those considered to have a significant role include Principal Investigators, Co-Principal Investigators, and any other person who is responsible for the design, conduct, or reporting of work performed on the project. In addition, the disclosure must be made for each investigator's spouse and dependent children.

The appropriate disclosure form is to be completed and submitted to the CSUSM Corporation Office of Sponsored Projects. Disclosures must be updated annually and as new reportable financial interests are obtained.

II. Financial Interest

Financial interest includes travel reimbursements, salary or payment for services outside the scope of the award, interests or ownership in business enterprises, and intellectual property rights.

A significant financial interest is defined as any financial interest that an investigator would have that would reasonably appear to be directly and significantly affected by the sponsored activities or any interest that an investigator would have in entities whose financial interest would reasonably appear to be directly and significantly affected by the sponsored activities.

III. Financial Conflict of Interest (FCOI) Disclosure Statement – National Science Foundation (NSF) and Public Health Service (PHS)

All persons who will have a significant role in the design and execution of a NSF and/or PHS funded project must file a disclosure statement of all financial interests that would reasonably appear to be directly or significantly affected by their activities. Such persons are required to complete the Conflict of Interest training and the training must be repeated every four years. The required training is satisfied by the successful completion of the

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NIH Financial Conflict of Interest Tutorial available at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

The Certificate of Completion (at the conclusion of the NIH Tutorial) and the completed COI Disclosure Form must be submitted to the CSUSM Corporation Office of Sponsored Projects prior to any work being done on the project. All submitted COI documentation will be maintained by CSUSM Corporation in the project file for the same period of time as the award record retention requirement.

IV. Review of Financial Disclosures

All Disclosure Forms will be reviewed by the Office of Sponsored Projects.

If the Investigator states on the form that there are no reportable financial interests related to the project, no further action will be taken and the form will remain in the project file.

If a related financial interest is reported on the form, the disclosure will be reviewed by the Conflict of Interest Review Committee (CIRC)¹ to determine if the nature of the Investigator's financial interest is such that a conflict of interest is unlikely to occur and would not compromise the quality and objectivity of the research, including not causing harm to the University or the misuse of state resources.

If it is determined that a conflict of interest is likely to occur, the CIRC will meet to review the potential conflict. On the basis of the review, the CIRC will recommend to the CSUSM Corporation Executive Director and the Provost, or designees, whether funding for the project shall be accepted or continued and, if so, what actions need to be taken to manage, reduce, or eliminate any such conflicts of interest. Recommended actions will be documented in a Resolution Plan that may include: public disclosure of the financial interest, monitoring of research by independent reviewers, modification of the research plan if necessary to avoid conflict of interest, disqualification from participation in the portion of the project that is affected by the significant financial interest, divestiture of significant financial interests, or severance of relationships that create actual or potential conflicts.

On completion of its deliberations, the CIRC shall file a report with the Provost and with the CSUSM Corporation Executive Director. At a minimum, the report by the CIRC will consist of:

- Name of Investigator
- Name of project, topic, or activity
- Period of performance
- Date reviewed by the CIRC
- Funds proposed or awarded
- Documents reviewed by the CIRC
- Nature of financial interest

¹ The CIRC consists of two faculty selected in consultation with Academic Senate, one administrator from CSUSM Corporation, AVPR, and VPFAS or designee.

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

V. Enforcement Mechanisms and Sanctions

No grant or contract will be accepted for submittal nor administered by CSUSM Corporation without full disclosure by the Investigator(s) as detailed in the applicable procedures. Failure to comply with this policy and its implementing procedures will result in non-acceptance by CSUSM Corporation of the grant or contract.

Potential violations of the Conflict of Interest Resolution Plan shall be handled by the AVPR, who monitors the state of academic freedom and professional responsibility at CAL STATE SAN MARCOS. The CSUSM Corporation Executive Director or designee, in consultation with the Provost or designee, will establish and enforce appropriate sanctions based on the specific conduct of an investigator failing to follow the approved Resolution Plan.

VI. Record Maintenance

All financial disclosure statements and records of all actions taken in reviewing statements plus any actions taken to resolve actual or potential conflicts of interest will be retained for a minimum of three years after the termination or completion of the related grant or contract. If any litigation, government action, or other controversy exists after such termination or completion, the records shall be retained for a minimum of three years after any such litigation, government action or controversy has concluded. In those cases where a granting or contracting agency requires a longer period of record retention, CSUSM Corporation Office of Sponsored Projects will comply with that agency's requirements.