

510-002-B: Governmental Financial Conflict of Interest Procedure

This procedure implements [CSU Systemwide Policy Sponsored Programs Financial Conflict of Interest for Investigators](#) (ICSUAM Policy #11010.02), specifically the portion of the policy governed by federal regulations; and also University Corporation Policy [510-000-A: Financial Conflict of Interest Policy for Government Funding](#), for disclosure filing, FCOI training and tracking.

Summary

Financial Conflicts of Interest Requirements: Federal policy requires 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.

This procedure applies to all Investigators (the principal investigator or project director, co-principal investigator, and any other personnel) 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.

At the time of this drafting, the following agencies are known to require governmental FCOI disclosure:

- a. NSF and all sub-agencies
- b. PHS and all sub-agencies
 - Other organizations following PHS regulations (refer to [Appendix 1: List of Entities Subject to PHS Regulations](#))

Process

1. Filing a Disclosure

Disclosure is the process of a PI, as defined above, completing and submitting a Financial Conflict of Interest form when the following occur:

- a. Public Health Services (PHS) disclosures:
 - Initial proposal (prior to award)
 - Non-competing continuations
 - Renewals
 - Supplemental funding
 - New personnel added (must be reported within 60 days of addition)
 - 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)
- b. National Science Foundation (NSF) disclosures:
 - Initial proposal (prior to award)
 - At least annually during the period of award
 - New personnel added
 - Any change in an investigator’s significant financial interests

The FCOI disclosure form can be found - <https://csumb.edu/compliance/coi-forms>

2. Training Requirement (PHS funding)

Each Investigator is to complete training:

- a. Prior to engaging in research related to any PHS funded grant, cooperative agreement or contract;
- b. At least every four (4) years thereafter; or

- c. Immediately (within 10 business days following the event that triggers the training requirement) when any of the following applies:
 - Policy is revised that affects requirements of Investigators; or
 - An Investigator is newly appointed at the University and transfers their PHS funding to CSUMB; or
 - An Investigator is newly appointed to a PHS funded research grant as the PI or key personnel; or
 - The University 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: <https://www.citiprogram.org/>

3. Management of FCOIs

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

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

4. Pre-Submission Procedures

- a. The PI and other investigators responsible for conducting research complete and sign the governmental FCOI form and provide it to SPO with their Grant Proposal Routing Form (aka Blue Sheet) to be included in the proposal routing/approval process.
- b. After the proposal review/approval routing is complete, the pre-submission governmental FCOI form is forwarded to University Corporation Human Resources.

5. Awarded Projects Procedures

- a. Upon receipt of an award that requires FCOI certification, the PI is notified to complete CITI COI training, if required by sponsor such as PHS, and every four years thereafter.
- b. Conflict of Interest requirements are included in the New Award Orientation document prepared by SPO.
- c. FCOI form is completed and signed by the PI at the New Award Orientation. Form is forwarded to University Corporation Human Resources.
- d. FCOI certification requirements for participating agencies are entered as project deliverables in Kualu.

6. Tracking and Monitoring

- a. Upon receipt of a grant award, FCOI forms and training requirements are entered into Kualu as a project deliverable.
- b. Documentation of completed CITI training will be included in the grant file and reconciled in Kualu as a completed deliverable.
- c. Periodic notification of COI obligations will be generated in Kualu and emailed to PIs.
- d. CITI will notify the PI of expiring COI Training.
- e. Periodic notification of past due FCOI forms and training will be sent to Department Chairs and College Deans.
- f. CITI completion reports will be generated from the CITI program on a quarterly basis and verified in Kualu.

Roles & Responsibilities

PI: During the life of a research project subject to this project, the PI/investigator is responsible for the following:

1. Complete the initial governmental FCOI form during the proposal review/approval process and/or prior to acceptance of the award;
2. Update the governmental FCOI as required above, under “1. Filing a Disclosure”;
3. Complete training for PHS funded awards, as required above, under “2. Training Requirements (PHS Funding);
4. If applicable, comply with any conflict management requirements as identified by an internal review committee.

Dean (or other administrator): Responsible for reviewing the governmental FCOI form during the proposal routing process and participating in the review and resolution of reported conflicts of interest. Facilitate completion of FCOI form and/or training when notified of potential delinquency.

University Corporation Personnel: Receive, review, sign off, and file governmental FCOI forms. Document the review and resolution of reported conflicts of interest.

Corporation, Post-Award Admin: Corporation, Post-Award Admin collaborates with SPO on compliance with the FCOI procedure, when necessary.

SPO: Responsible for ensuring that the initial governmental FCOI form is obtained from the PI/investigator, for proposals for NSF funding and/or PHS funding (or entities adopting PHS regulations). In addition, SPO will:

1. forward the initial original governmental FCOI form to University Corporation HR with “Proposal” written on it for UCorp HR to maintain;
2. include conflict of interest information in the New Award Orientation document, review the requirements during the orientation and have the PI complete and sign an awarded governmental FCOI form;
3. forward the awarded FCOI form, to UCorp HR with “Award” written on it;
4. In Kualī – track the requirement of the disclosure/form completion and training/completion; ensure that CITI and Kualī notifications are sent to investigators to facilitate compliance.

References

For Sponsored Programs Policy Definitions, refer to CSU [Sponsored Programs Policy Definitions](#) (ICSUAM #11001.01).

Policy/Regulation Links:

1. NSF (National Science Foundation) Conflict of Interest Regulations: https://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/aag_4.jsp
2. PHS (Public Health Service) Financial Conflict of Interest Regulations: <https://grants.nih.gov/grants/policy/coi/index.htm>
3. CSU Conflict of Interest Handbook (COI code): <https://www2.calstate.edu/csu-system/administration/general-counsel/Documents/ConflictofInterestHandbook.pdf>
4. CSU Sponsored Programs FCOI for Investigators Policy: <https://calstate.policystat.com/policy/6594777/latest/>
5. Refer to UCorp Policy [521-003-A: Financial Conflict of Interest Policy for Government Funding](#) for more information regarding reporting requirements.

Forms & Training Links:

Governmental FCOI disclosure form - <https://csumb.edu/compliance/coi-forms>

The PHS Conflict of Interest course on the Collaborative Institutional Training Initiative (CITI) site: <https://www.citiprogram.org/>

Guidelines

Summary of Disclosure Requirements: Refer to the CSU FCOI Disclosure Chart for summary of requirements by funding source. [CSU FCOI Disclosure Requirements by Funding Source Chart](#)

Appendix 1: List of Entities Subject to PHS Regulations

Disclaimer: This list of PHS agencies is adapted from the [US Department of Health and Human Services Organizational Chart](#). Due to periodic organizational restructuring, this list may change.

U.S. Public Health Services Agencies:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs
- Office of the Assistant Secretary for Health, including
 - Office of Minority Health Resources Center (OMH)
 - Office of Population Affairs (OPA)
 - Office of Research Integrity (ORI)
 - Office of Research on Women's Health (OWH)
- Office of the Assistant Secretary for Preparedness and Response, including
 - Biomedical Advanced Research and Development Authority (BARDA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Currently known non-PHS organizations which have adopted PHS regulations regarding COI (from [UCOP Research Policy & Analysis list](#)) – refer to private entity guidelines for specific requirements:

- Alliance for Lupus Research
- American Cancer Society (ACS)
- American Heart Association (AHA)
- American Lung Association (ALA)
- Arthritis Foundation
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of America
- Susan G. Komen for the Cure