

Financial Conflict of Interest (FCOI) Internal Procedures

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Revisions:

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SUMMARY:

Background

- Applicability: These procedures apply to employees submitting proposals for external funding at Cal State East Bay, managed by the Office of Research and Sponsored Programs (ORSP).
- Regulations: Compliance with federal, state, CSU, and institutional policies is required, including FCOI disclosure and training based on sponsor-specific requirements.

FCOI Training Requirements

1. Mandatory Training:

- CSU Ethics/COI training every two years for all PIs, including those funded by private businesses or nonprofits.
- CITI COI training every four years for PIs receiving PHS (e.g., NIH) or Department of Energy funding.
- NSF-funded investigators may take either CSU Ethics/COI or CITI training, with CSU Ethics/COI preferred.

Procedures

1. Proposal Review and Submission:

- PIs initiate proposals via Cayuse, ensuring data collection and compliance notifications.
- Completion of COI disclosures through Cayuse Outside Interests is mandatory.
- Subrecipient PIs must disclose conflicts and confirm compliance with FCOI training.

2. Award Negotiation and Acceptance:

- ORSP reviews FCOI compliance, including training and disclosures, before award acceptance.

3. Performance Period:

- Annual updates to COI forms, as required by sponsors.
- Newly identified SFIs must be disclosed within 30 days.

4. Disclosure Management:

- SFIs disclosed are reviewed by the Institutional Official (IO) or designee, who drafts a management plan if needed.

- Management plans include investigator, department chair, dean, and Provost review and approval.

- Reports on FCOI disclosures are submitted to funding agencies as required.

5. Non-Compliance:

- Non-compliance triggers review, corrective actions, and notification to funding agencies.

- Retrospective reviews address late disclosures or unreported SFIs.

6. Public Disclosure (PHS/DOE):

- FCOI details of funded projects are publicly accessible, updated annually, and within 60 days of new disclosures.

- PIs must complete COI disclosures in the Cayuse Outside Interests module.

- Subrecipient PIs must complete a commitment form indicating whether their institution's COI policy meets requirements. If not, they must complete CSUEB training.

- Updates to COI disclosures must be submitted within 30 days of identifying or acquiring a new significant financial interest.

Record Retention

Records are retained for at least three years post-final expenditure report submission or as stipulated by regulations.

Roles

- Institutional Official (IO): Reviews disclosures and oversees management plans. In addition to reviews, ensures compliance by reporting to agencies and managing corrective actions for non-compliance.

- ORSP Staff: Facilitate training, disclosures, and compliance for CSUEB Investigators; Oversees subrecipient COI compliance and ensures timely updates in Cayuse.

- Principal Investigators (PIs): Ensure compliance for themselves and project team members.

- Investigators: Ensure training completion and SFI disclosure for themselves.

Training Expirations

- PHS/DOE-funded PIs: CITI training every four years; CSU Ethics/COI every two years.

- NSF/private-funded PIs: CSU Ethics/COI training every two years.

For additional detailed information, if needed, please see the next pages.

Background

Employees who submit proposals for external funding for their research, scholarship, or creative activities and community service are known as Principal Investigators (PIs) or Project Directors (PDs). At Cal State East Bay the Office of Research and Sponsored Programs (ORSP), assists PIs and PDs with their proposal submissions. There are numerous federal, state, local, CSU, and campus policies and regulations with which to adhere during the proposal and award acceptance processes.

Cal State East Bay policy [19-20 CR 3](#), approved by the Academic Senate, describes the requirement to comply with regulations, including those related to disclosing potential financial conflicts of interest. Federal agencies and other sponsors who provide external funding have different Financial Conflict of Interest (FCOI) requirements, so for each proposal ORSP and investigators need to confirm which FCOI regulations apply. These procedures further describe FCOI training requirements, regulations, investigator disclosure responsibilities, and how to submit a Financial Conflict of Interest Disclosure.

FCOI Training Requirements

All Principal Investigators:

Irrespective of funding source, all Principal Investigators are required to complete training on CSU Ethics/COI (available through CSULearn). This includes PIs funded by a private business or non-profits not on the FPPC Exempt organization list must take the CSU/Cal State East Bay Ethics/COI training every 2 years.

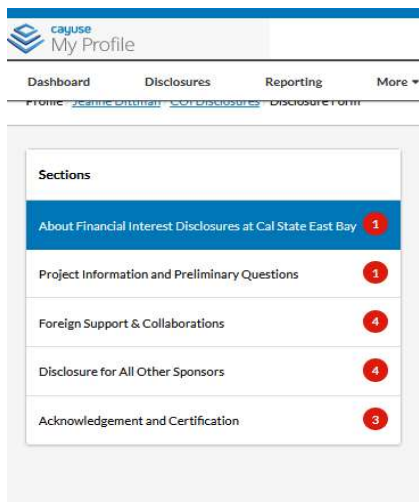
Investigators receiving funding from PHS (e.g., NIH) or Dept of Energy need to take the PHS-compliant / Dept of Energy-Compliant FCOI training every 4 years, in addition to taking the (CSULEARN) CSU/CSUEB Ethics/COI training every 2 years. CITI COI Training (available through CITI)

Investigators receiving funding from the National Science Foundation may take either the CSU Ethics/COI training or the CITI COI Training. CSU Ethics/COI training (via CSU Learn) is preferred.

Procedures

During Proposal Review, Routing, and Submission

1. As soon as it is determined a proposal for external funding might be submitted, PIs log on to Cayuse Sponsored Programs (SP) and begin entering information about the proposal. The entry into Cayuse SP alerts ORSP of the PI's intent and collects all of the project and project team information that may be needed for a successful proposal submission.
2. PI's will also need to complete conflict of interest disclosures in Cayuse Outside Interests module in Cayuse: <https://csueastbay.app.cayuse.com/profile/#disclosures>
Once PIs log on to Cayuse Outside Interests they will follow the steps to choose their sponsor and sponsor type, and to list their SFIs, if any.



3. PIs are responsible for completing COI training as required by PHS, NSF, the Dept of Energy, the State of California for private funding, and other sponsors. All Cal State East Bay investigators are required to be compliant with FCOI training requirements prior to award acceptance.

If the required training is not completed before submission, the PI must notify ORSP of when the training will be done and ensure completion. If you don't know if you've completed your training, please login to your [CSU Learn portal](#) to confirm.

4. Upon completion of training, CITI and Cayuse will sync and update records. For the CSU Learn CSU Ethic/COI training, investigators may upload a copy of the training certificate upon completion to their Cayuse COI OI Profile. ORSP will also update training records on the Cayuse COI system, as needed.

5. AVP ORSP or designee will review submissions of Conflict of Interest disclosures that disclose significant financial interests (SFIs) or other conflicts of interest and determine next steps, which often include FCOI Management Memos to document mitigation or management of perceived Conflict of Interests

6. Conflict of interest disclosures are also required from subaward teams.

- For any proposed subawards identified, a subrecipient commitment form is required that indicates whether the subrecipient PIs will follow their institution's or CSUEB's COI policy.
- When pre-award staff are unsure whether a subrecipient's policy meets COI requirements, they may contact the ORSP Compliance Specialist, who can help confirm compliance.
- If the subrecipient's policy does not comply with the training requirement, the pre-award staff will request subrecipient investigators complete CSUEB COI training. If this training is not completed before submission, the subrecipient PI must notify ORSP of when the training will be done and complete it as soon as possible prior. Lack of training certification will cause delays to the acceptance of a grant award.

During Award Negotiation and Acceptance

1. Prior to award acceptance, ORSP staff review award compliance including FCOI requirements and confirmation of training completion. If the training is not yet complete, award acceptance may be delayed

During PI Orientation and the Performance Period

1. During award orientation, post-award staff will review the training status again to confirm completion, and will review the completed Conflict of Interest forms with the PI to make sure they are current. Post award staff will also remind PIs to review FCOI policies (see ORSP policies website) with PI's and senior key personnel.
2. All project team members who are required to disclose significant financial interests may use the Cayuse Outside Interest-COI (OI/COI) module to submit their disclosures.
 - a. PIs should notify ORSP Pre-Award or Post-Award staff of anyone needing to be added to the Cayuse OI-COI module.
 - b. In the event of an amendment to the award, during proposal submission or award acceptance investigators must submit updated forms if the prior submitted COI form is a year old or more or if any circumstances have changed.
3. Within 30 days of discovering or acquiring a new significant financial interest, the PI or any senior key personnel or investigator included in the requirement must complete a COI update using the Cayuse OI/COI system.
4. The ORSP Post Award and ORSP Compliance staff will work together to ensure updated Conflict of Interest forms are received from PIs for sponsors requiring annual disclosures prior to COI expiration.
5. Cal State East Bay employees can go into the Cayuse OI-COI module at any time and create and update their specific or generic Financial Conflict of Interest Disclosure information and should do so when SFIs change to ensure their disclosures are up to date to accommodate their sponsored program funding plans.

Upon disclosure of a Financial Conflict of Interest/Significant Financial Interest

1. Once a significant financial interest (SFI) is disclosed in the Cayuse OI-COI module, the information routes to the AVP ORSP (Institutional Official - IO) or designee, e.g. Director, Compliance and Standards, who will review the disclosure and provide an initial determination and management plan recommendation to the AVP Office of Research and Sponsored Programs (AVP ORSP).
2. The IO will review the disclosure and recommendations to determine whether a financial conflict of interest exists that could directly and significantly affect the design, conduct, or reporting of the funded research.
3. The IO will review disclosures that are made at any point during the proposal and award stages or during the period of performance.
4. Within 60 days of the SFI disclosure, the IO will complete the review and will collaborate with the PI or other investigator to develop a written management plan to mitigate the actual or perceived FCOI.
5. The written management plan to mitigate the actual or perceived FCOI will be reviewed and signed by the Investigator, Department Chair, Dean, AVP ORSP, and the Provost. When

applicable, the PI or the department chair may be assigned project oversight over the investigator activities.

6. Three key identifiers of an active FCOI are as follows:
 - The significant financial interest was disclosed and is still held by the senior/key personnel as defined by federal or other regulations; and
 - The Institution determines that the significant financial interest is related to the Sponsored Program; and
 - The Institution determines that the significant financial interest is a financial conflict of interest.

7. The AVP ORSP (Institutional Official - IO), will provide reports to federal, state, or local agencies as required to report SFI disclosures, management plans, and subsequent changes.
 - If a situation occurs in which an investigator fails to comply with the FCOI policy or procedures or a FCOI management plan appears to have biased the design conduct, or reporting of a PHS- or NSF- or other funded research, the IO will ensure the awarding agency component is promptly notified of the situation and corrective action taken or to be taken. (For example, NSF's Office of the General Counsel (OGC) or an NIH Grant Officer.)

8. If a situation of investigator non-compliance occurs, the IO will ensure that adequate allowable sanctions or administrative actions are taken to ensure investigator compliance occurs.

9. When it is discovered an SFI was not disclosed in a timely manner, the IO will ensure that the review, management plan development, and documentation occurs within 120 days of the determination of noncompliance for SFIs not disclosed timely. Documentation of the review will include the following required elements:
 - (1) Project number;
 - (2) Project title;
 - (3) PI or Co-PI (person to contact);
 - (4) Name of the Investigator with the FCOI;
 - (5) Name of the entity with which the Investigator has a financial conflict of interest;
 - (6) Reasons for the retrospective review;
 - (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - (8) Findings of the review; and
 - (9) Conclusions of the review.

10. While Cal State East Bay does not often participate in clinical research, should a case occur in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with an SFI that was not managed or reported by the institution as required by the regulations, the IO will notify the investigator that the investigator involved is required to disclose the FCOI in each public presentation of the results of the research, and must request an addendum be added to previously published presentations.

Public Disclosure of Financial Conflicts of Interest

Projects funded by Public Health Service agencies (such as NIH) or by the Department of Energy (DOE):

The IO will ensure that information regarding FCOIs held by PHS- or DOE-funded senior/key personnel will be publicly accessible prior to the expenditure of funds. Public website posting will be reviewed and updated annually and within 60 days of new identified and confirmed FCOIs, and the information retained for 3 years after the final FCOI update.

The following minimum elements will be provided by a posting on the Cal State East Bay website, or made available in writing upon request within 5 calendar days of the written request.

- the Investigator's name;
- the Investigator's title and role with respect to the research project;
- the name of the entity in which the significant financial interest is held;
- the nature of the significant financial interest;
- and the approximate dollar value of the significant financial interest (Permissible dollar ranges include the following:
 - \$0-\$4,999;
 - \$5,000-\$9,999;
 - \$10,000-\$19,999;
 - amounts between \$20,000-\$100,000 by increments of \$20,000;
 - amounts above \$100,000 by increments of \$50,000),
 - or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Projects funded by National Science Foundation:

PIs should note that FCOI Significant Financial Interest disclosure information may be released or transmitted to the sponsor, including federal research funding agency representatives, and, according to state law, may also be released to the public upon request.

Record Retention

FCOI-compliant records will be retained for at least 3 years from the date the final expenditures report is submitted to the funding agency, or as specified in as applicable to [45 CFR 74.53\(b\)](#) and [CFR 92.42\(b\)](#).

Regulations:

California State of Economic Interests:

[FPPC-700U](#)

Federal:

[2-CFR-200.112](#)

Public Health Service (PHS) - [42-CFR 50.604 - 42-CFR 50.606](#)

National Institutes of Health - [42 CFR 50-Subpart F](#) and [NIH FCOI Compliance Checklist National Science Foundation \(NSF\) - Proposal and Award Policy and Procedure Guide Conflict of Interest](#)

Roles:

AVP Office of Research and Sponsored Programs (Institutional Official [IO]) or designee – Performs initial review of FCOI disclosures, consults on determination, and provides management plan recommendations to AVP ORSP.

AVP Office of Research and Sponsored Programs (Institutional Official [IO]) - Reviews financial conflict of interest disclosures, creates and monitors management plans to mitigate actual or perceived conflicts of interest.

Investigator and others project team members as required - Discloses significant financial interests and complete required training.

ORSP staff - Ensures PIs and other required investigators are aware of FCOI regulations, receive training, and submit required FCOI disclosures using the Cayuse OI-COU module.

Principal Investigator - Ensures they and all required investigators and other team members on their projects who are required to do so submit FCOI disclosures, update disclosures when a Significant Financial Interest occurs, and completes training.

Training Expiration:

- PIs only submitting proposals to or receiving funding from PHS or DOE need to take the PHS-compliant / DOE-Compliant (CITI) FCOI training every 4 years, in addition to taking the (CSULEARN) CSU/CSUEB Ethics/COI training every 2 years.
- PIs only submitting to NSF and private entities are required to take the (CSULEARN) CSU ethics training every 2 years.