



Financial Conflict of Interest (FCOI) Disclosure and Training Internal Procedures

June 22, 2018

Revisions:

November 30, 2020

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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

CSU Ethics/COI (available through CSULearn) (PIs funded by a private business or non-profit)

- All Cal State East Bay Principal Investigators receiving funding from a private business or non-profit not on the FPPC Exempt organization list must take the CSU/Cal State East Bay Ethics/COI training every 2 years.

CITI COI Training (available through CITI) (Required for PHS-funded Investigators or Dept of Energy-funded Investigators)

- 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.
- Investigators receiving funding from the National Science Foundation may take either the CSU Ethics/COI training or the CITI COI Training.

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 and begin entering information about the proposal.
 - The entry into Cayuse 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.
 - The Conflict of Interest section of the proposal submission, which used to present questions to help guide investigators through their required financial disclosures, now directs them to and provides a link to the separate Cayuse "Outside Interests" Conflict of Interest module, as shown in the screenshot that follows:

>> 4. Conflict of Interest

Required Collaborations Disclosure Instructions:
If any member of your research team is an employee of another CSU Campus or auxiliary, then Navigate to "Optional: Submission Notes" in your Cayuse proposal. Add a note that begins with "Collaborations within CSU" and list the team members and their CSU or auxiliary. ORSP will follow up with the Sponsored Programs team at each campus. Make sure you also follow the Conflict of Interest Disclosure Instructions below.

Required Conflict of Interest Disclosure Instructions:

1. Make note of the Cayuse proposal number (format: ###-####).
2. When applicable, notify all key personnel in this proposal that they are required to provide Financial Conflict of Interest (FCOI) disclosure information. Key personnel include: PI, Co-PI, Investigators and others who make research decisions or as applicable to your sponsor's Conflict of Interest Policy. Requirements may be in the opportunity announcement and guidance is also found in the COI Disclosure module.
To notify project team key personnel, you may use this sample email text:
Please follow this Disclosure Module link (<https://cayusebay.spc.cayuse.com/profile/#disclosure>) to complete your Financial Conflict of Interest (FCOI) disclosure information for our proposal number _____. In the COI Disclosure Module, you will choose your sponsor type, enter the number of this proposal, and answer questions about any income you may receive or financial connections you may have that are related to the sponsor, your proposal, and your institutional responsibilities. FCOI disclosures are required, regardless of whether there is a conflict to report. Proposals will not be submitted or awards will not be accepted without complete FCOI disclosures.
3. Click on this Disclosure Module link (<https://cayusebay.spc.cayuse.com/profile/#disclosure>) and follow the instructions to complete your own FCOI disclosure.

Effective 12/1/2021 the Cayuse COI questions below are no longer in use. Follow the instructions above.

* Indicates Required Fields

None of the questions below are required.

1. Currently or during the term of this research project, does any member of the research team or his/her family member have or expect to have:
 - a. A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study?
 Yes No
 - b. A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project?
 Yes No
 - c. A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project?
 Yes No
 - d. A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the subcontractor/consultant for this project?
 Yes No
2. Is any member of the research team an employee of another CSU campus?
 Yes No
3. Has the University or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project?
 Yes No

Save Reset

2. PIs click on the disclosure module link to use the Cayuse Outside Interests module to create FCOI disclosures to list their Significant Financial Interests or to indicate they do not have any. 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.

My Profile

Dashboard Disclosures Reporting More

Sections

- About Financial Interest Disclosures of Cal State East Bay 1
- Project Information and Preliminary Questions 1
- Foreign Support & Collaborations 4
- Disclosure for All Other Sponsors 4
- Acknowledgement and Certification 5

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.
 - If the required training is not completed before submission, the PI must notify ORSP of when the training will be done and ensure completion.
 - All Cal State East Bay investigators are required to be compliant with FCOI training requirements prior to award acceptance.
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 monthly.
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

7. 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

8. During the award orientation meeting, 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.

- All project team members who are required to disclose significant financial interests may use the Cayuse Outside Interestst-COI (OI/COI) module to submit their disclosures.
 - PIs should notify ORSP Pre-Award or Post-Award staff of anyone needing to be added to the Cayuse OI-COI module.
9. 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.
 10. 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.
 11. The ORSP Post Award and ORSP Compliance staff will work together to ensure updated Conflict of Interest forms are received from PIs on active awards annually prior to COI expiration.
 12. 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 at any time and should do so when SFIs change and at least once a year 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

- 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).
- 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.
 - The IO will review disclosures that are made at any point during the proposal and award stages or during the period of performance.
 - 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.
 - 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.
 - Three key identifiers of an active FCOI are as follows:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by federal or other regulations; and

(B) The Institution determines that the significant financial interest is related to the Sponsored Program; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

- 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.)
- 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.
- 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.
- 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.