



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

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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 East Bay 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 regulations, investigator disclosure responsibilities, and training requirements.

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 only)

- Investigators receiving funding from PHS (e.g., NIH) need to take the PHS-compliant FCOI training every 4 years, in addition to taking the CSU/CSUEB Ethics/COI training every 2 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 presents questions to help guide investigators through their required financial disclosures, as shown in the screenshot that follows:

Instructions

1. Answer the questions below
2. Complete a Conflict of Interest Form for [NSF](#), [PHS](#), or a [700U](#) for all other sponsors, for each key project team member
3. Upload form(s) to Proposal Attachments section
4. Continue to 5. Regulatory Compliance (Item List, to left)

Please email [ORSP](#) staff for assistance with additional questions about Conflict of Interest.

* Indicates Required Fields

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

2. When one or more of the answers to the questions listed in 1. above are “Yes”, the investigator will be required to complete the additional Financial Conflict of Interest form to fulfill the specific funder requirements, which vary depending on the sponsor to which the proposal is being submitted. The most common formats are found at links within Cayuse, for example, [NSF](#), [PHS](#), [Corporate and Private Funders](#).
3. Once ORSP preaward staff begin reviewing the submittal, if it does not look as though COI training is up to date, ORSP staff will provide PI's, Investigators, and Senior Key Personnel with additional instructions on how to complete or refresh their appropriate COI training as required by the CSU, PHS, NSF, or 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 must submit a copy of the certificate of completion to ORSP pre-award staff.
5. Preaward staff will ensure Cayuse is updated with the training information and forward the CSU Learn certificate to the ORSP Compliance Specialist.

6. Preaward staff will review the Conflict of Interest information submitted through Cayuse and ensure that the investigators have submitted the appropriate Financial Conflict of Interest forms (700-U, ORSP NIH or ORSP NSF) as applicable prior to proposal submission.

7. 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

8. Prior to award acceptance, pre-award staff will review Cayuse to confirm confirmation of training completion. If the training is not yet complete, award acceptance may be delayed. The ORSP Director, Grant Administration will review the award and work with pre- and post-award to ensure compliance prior to accepting the award.

9. During processing of proposals and awards, if staff find that a training date is missing or expired, post-award staff will send an email to the PI(s) and senior key personnel (copying the ORSP Compliance Specialist) requesting the COI training be completed prior to conducting any work on the award.

During PI Orientation and the Performance Period

10. 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.

11. On a quarterly basis, ORSP Post Award and the Compliance Specialist will review the Conflict of Interest forms and training statuses and send reminders to the appropriate PIs and key personnel about completing COI training and COI forms (CA 700-U or sponsor-specific disclosure form) prior to the annual due dates.

12. 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.

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13. 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 system to alert the ORSP team.

- The ORSP pre-award team will alert the ORSP Compliance Specialist who will collect updated COI disclosure forms. The Specialist will review the training status and will follow up with the investigator(s) if training has not yet been completed.

14. The ORSP Compliance Specialist will work with the Post-Award staff to ensure updated Conflict of Interest forms are received from PIs on active awards annually prior to COI expiration.

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

- Once a significant financial interest (SFI) is disclosed, the ORSP staff will provide the disclosure to the AVP of Research and Sponsored Programs.
- The AVP of Research and Sponsored Programs (Institutional Official - IO), will review the disclosure 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 of Research and Sponsored Programs, 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 Research; and
 - (C) The Institution determines that the significant financial interest is a financial conflict of interest.

- The AVP of Research and Sponsored Programs (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 CSUEB does not normally 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 - Required for PHS-Funded Projects*
 - The IO will ensure that FCOIs held by PHS-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.

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 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 - 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.

Principal Investigator - Ensures they and all required investigators 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 need to take the PHS-compliant FCOI training every 4 years, in addition to taking the CSU/CSUEB Ethics/COI training every 2 years.
- PIs only submitting to NSF and private entities are required to take the CSU ethics training every 2 years.