



<b>Procedure Title</b>	Process for Financial Conflicts of Interest in Research
<b>Date of Review</b>	17 October 2022
<b>Responsible Office</b>	Research Compliance
<b>Contact Information</b>	<a href="mailto:researchcomp@kennesaw.edu">researchcomp@kennesaw.edu</a>

Abbreviations:

1. COI: Conflict of interest
2. SFI: Significant financial interest
3. FCOI: Financial conflict of interest
4. CITI: Collaborative Institutional Training Initiative – vendor for research compliance training
5. VPR: Vice President for Research
6. PI: Principal Investigator
7. ADR: Assistant/Associate Dean for Research

Goals:

1. Ensure that all individuals who provide effort on a federal award have up-to-date COI disclosures on file in Cayuse, defined as a disclosure submitted within the last year. A researcher without SFIs to disclose needs to attest to this via the disclosure process.
2. Ensure that external funding proposals are not submitted without up-to-date COI disclosures on file in Cayuse for all individuals identified as providing effort on the project.
3. Ensure that all researchers providing effort on external awards are up to date on FCOI training (via CITI).
4. Ensure that all researchers providing effort on external awards disclose any new SFIs within 30 days.
5. Review any disclosures of SFIs to determine if they do indeed represent conflicts of interest and manage as needed.
6. Report any managed or unmanageable SFIs to the appropriate funding agency per their reporting procedures.

Processes:

1. Research Compliance will advertise annual disclosure campaigns each January:
  - a. All researchers are reminded to update their disclosures, whether or not there are any changes.
  - b. All researchers are reminded to verify that their CITI FCOI training is not expired.
  - c. Communicate a) and b) via general university communication systems and Research Listserv.
  - d. Remind Research Advisory Committee to encourage researchers in their colleges to file disclosures.
  - e. Reach out to individual researchers listed as providing effort on active grant awards who do not file and/or who have lapsed training by mid-January (list of active awards and personnel to be provided by Post-Award staff). Include in message reminder that all key personnel on the award need to file disclosures and complete training.
  - f. Report list of continued non-compliant researchers to the VPR in the last two weeks of January.
  - g. VPR will email the PI and copy the ADR of the College to request compliance.
2. Research Compliance will follow up with active award holders and those providing effort on federal awards in July reminding them to update disclosures & training on an as-needed basis. List of active awards and personnel to be provided by Post-Award staff.

- a. Personalized messages sent addressing individual disclosure and training status, notifying that they have two weeks to comply. Include in message reminder that all key personnel on the award need to file disclosures and complete training.
  - b. Message will include reminder to disclose any newly acquired SFIs within the prescribed 30-day timeframe.
  - c. Post reminder to disclose new SFIs on general university communication systems and Research Listserv.
  - d. Report list of continued non-compliant researchers to the VPR in the last two weeks of July.
  - e. VPR will email the PI and copy the ADR of the College to request compliance.
3. Pre-award has a checklist item to look for FCOI disclosures as they finalize funding proposals.
    - a. Appropriate training and/or instructional references on Cayuse system provided to pre-award staff by Research Compliance.
    - b. Any proposal that is lacking a required FCOI disclosure will not be submitted, whether or not the proposal deadline is imminent.
    - c. Notification to PI, Chair, Dean, and ADR of the reason for non-submission.
  4. Post-award can remind faculty and verify FCOI disclosure status in Cayuse.
    - a. At time of award, verification of FCOI disclosures by all key personnel on the project (those providing effort) must be complete before money can be spent.
    - b. Issue reminders to regularly review and update FCOI disclosures at points of contact.
    - c. Appropriate training and/or instructional references on Cayuse system provided to post-award staff by Research Compliance.
  5. Review of FCOIs is accomplished via Cayuse
    - a. Disclosures that report no SFIs are resolved as “No COI determined.”
    - b. Research Compliance reviews disclosures that do list SFIs, notes whether conflict is present or apparent.
      - i. Research Compliance then sends to other members of the FCOI Committee for review & comment (training/instructional materials provided as needed).
      - ii. Research Compliance determines whether the disclosure needs more information from the researcher or can be resolved as is.
      - iii. If a management plan is required, then a template is provided to the researcher for completion and subsequently approved by the signatories on the plan.
      - iv. Completed, approved management plans are routed for signatures, then attached to the disclosure in Cayuse.
      - v. Periodic communications with PI, key personnel, and others involved in any management plan (timeframe to vary by the plan specifics) to verify adherence to terms.
      - vi. Any disclosures resolved as “COI determined, unmanageable” or “COI determined & managed” will be reported to the appropriate agency according to their requirements and procedures by Research Compliance.