



<b>Policy Title:</b>	<b>Financial Conflict of Interest in Sponsored Research (FCOI)</b>
<b>Policy Number:</b>	ACAD- 132
<b>Revision Date:</b>	February 2022
<b>Policies Superseded:</b>	ACAD-307
<b>Policy Management Area(s):</b>	Research

**SUMMARY:**

This policy aims to promote objectivity in research by establishing standards to ensure there is a reasonable expectation that the design, conduct, or reporting of research results will not be biased by any conflicting financial interest of an investigator.

**POLICY:**

**I. DEFINITIONS**

- A. Financial Conflict of Interest (FCOI)- Exists when a significant financial interest, defined below, could directly and significantly, affect the design, conduct, or reporting on results of funded research or educational activities.
- B. Investigator- the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research results.
- C. Research- Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- D. Significant Financial Interest (SFI)- A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse, partner, and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:
  - 1. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000 (or \$10,000 in the case of NSF funding). For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - 2. With regard to any non-publicly traded entity, an SFI exists if the value of any

remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000 (in the case of NSF funding, \$10,000), or when the Investigator (or the Investigator's spouse, partner, or dependent children) owns any equity interest, regardless of dollar value (or in the case of NSF funding, more than 5% ownership interest in any single entity); and/or

3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. *SFI* does not include:
  - a. Salary, royalties, or other remuneration paid by Coastal Carolina University to the Investigator if the Investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;
  - b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
  - c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
  - d. Income from service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

E. University Reviewer- the Associate Provost for Research or their designee(s).

## II. FCOI RESPONSIBILITIES:

All faculty, staff, and students responsible for the design, conduct, or reporting of research results under the terms of a grant or contract are required to disclose to the Associate Provost for Research all significant financial interests (SFI), as defined in this policy, of the Investigator or the Investigator's spouse, partner, or dependent children.

### A. Required Financial Disclosure

1. Investigators must provide all required financial disclosures by completing the Financial Conflict of Interest Disclosure form found on the Office of Sponsored Programs and Research Services (OSPRS) website at the time a funding proposal is being prepared for submission.
2. Investigators must update the Disclosure form:
  - Within thirty (30) days of discovering or acquiring (e.g., through purpose, marriage, or inheritance) any new SFI; and
  - Annually within the period of the award, beginning with the anniversary date of the original disclosure.

## B. Review of Financial Disclosures

1. The University Reviewer shall review each disclosed SFI and determine whether an FCOI exists. The University Reviewer may request that additional staff or faculty serve on an ad hoc review committee to assist in timely review.
2. Management of Financial Conflicts of Interest  
If the University Reviewer determines that an SFI constitutes an FCOI, they will convene a committee consisting of faculty, staff, and/or outside experts whose make-up the University Reviewer shall determine. The committee will review the research, the SFI in question, and the areas of conflict to devise a plan for the management of the FCOI.

The management plan may include conditions or restrictions to manage, reduce, or eliminate the FCOI, which may include, but are not limited to:

- a. Monitoring of research by independent reviewers;
- b. Modifying the research plan;
- c. Disqualifying the portion of the funded research that would be affected by an SFI;
- d. Reducing or eliminating the SFI;
- e. Severing the relationship(s) that creates conflict; or
- f. Offering a public disclosure of the FCOI.

The Investigator shall be consulted on the management plan and must agree to the plan before the research can proceed. If the committee and the Investigator cannot agree upon a management plan, the relevant regulatory bodies and funding agency will be notified.

## C. Reporting of Financial Conflicts of Interest

### 1. Sponsoring Agency

SFI that are determined by the University Reviewer to be an FCOI will be reported to the sponsoring agency in accordance with its requirements within sixty (60) days of the original disclosure.

### 2. Public Request

As required by sponsoring agency regulations, information on the nature of such FCOIs will be made available to members of the public by the University Reviewer in response to inquiries specifying the Investigator name and the research project in question within five (5) business days of receipt of such requests.

#### D. Investigator Non-Compliance

1. If the University Reviewer determines that an FCOI was not identified or managed in a timely manner, including, but not limited to, an Investigator's failure to disclose an SFI that is later determined to be an FCOI, or failure by an Investigator to materially comply with a management plan for an FCOI, a committee appointed by the University Reviewer will complete a retrospective review of the Investigator's activities.
2. The review of the research project will determine whether the research conducted during the period of non-compliance was biased in the design, conduct, or reporting of results. Documentation of the retrospective review shall include:
  - Investigator name;
  - Grant number;
  - Project title;
  - Name of the Investigator with the FCOI;
  - Name of the entity with which the Investigator has the FCOI;
  - Reason(s) for the retrospective review;
  - Detailed methodology used for the retrospective review; and
3. Findings and conclusion of the review.
  - a. If the retrospective review involves a Public Health Service (PHS) agency (e.g., FDA, NIH, etc.), the University Reviewer shall update any previously submitted report to the PHS or the prime PHS-awardee (if Coastal Carolina University is a subrecipient) relating to the research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.
  - b. In the event of an Investigator's failure to comply with this policy, the University Reviewer, in consultation and coordination with the Investigator's supervisor and the university's Authorized Organization Representative (AOR), may suspend all relevant activities and/or refer the matter to the appropriate Dean or Department Head for disciplinary action in accordance with university employment policy and the current Faculty Manual, as applicable.

#### E. Records

The University shall maintain records of all financial disclosures and of all actions taken to resolve the FCOI for at least three (3) years beyond the termination or completion of the grant to which they relate, until the resolution of any federal action involving those records, or in accordance with the university record retention schedule, whichever is longer.

#### F. Training

##### 1. Investigators on NIH/PHS proposals

Each Investigator on projects funded by or proposed to NIH or other [PHS-affiliated agencies](#) must complete training on FCOI. Investigators must complete such training prior to participation in PHS-funded research and every four (4) years thereafter as long as the project is active. This educational requirement is met by completing the

“Financial Conflicts of Interest” course located on the Collaborative Institutional Training Initiative (CITI) website. Instructions for registering and taking this course can be found on the OSPRS website.

2. Investigators on Non-NIH/PHS proposals

For Investigators sponsored by or seeking funding from other federal agencies, as well as any Investigators initiating research sponsored by a state, local, foundation, or for-profit entity, training activities are optional but highly recommended.

G. Subrecipient

The university is responsible for ensuring all subrecipients’ compliance with the applicable federal regulations regarding an FCOI. To this end, the university shall include, as part of the subrecipient commitment form, confirmation that the subrecipient institution has a compliant policy or will apply this policy to the subrecipient Investigators.

III. RELATED INFORMATION

A. National Institutes of Health (NIH) – [grants.nih.gov/grants/policy/coi/](https://grants.nih.gov/grants/policy/coi/)

B. National Science Foundation (NSF) – [Conflict of Interest Policy](#)

C. [42 CFR Part 50 Subpart F - Promoting Objectivity in Research](#)

D. [45 CFR Part 94 – Responsible Prospective Contractors](#)