



## Financial Conflict of Interest Committee Guidelines

### Mission

*The Financial Conflict of Interest Committee (FCOIC) implements the University's Conflict of Interest regulations and policies to promote research to be conducted with the highest ethical standards, objectivity, and professional integrity while supporting university missions of world-class research, commercialization, economic growth, and preservation of trust from the public and scientific community.*

### Purpose

The purpose of the university-wide committee is to review and make decisions relative to disclosures of potential conflicts of interest in research and sponsored programs. Members of the Committee bring a much-needed perspective to identify significant financial interests of investigators that could affect the design, conduct or reporting of sponsored funded research. Their contributions help the university to meet Federal and State compliance requirements and to ensure the integrity of University of Central Florida's research and development programs in accordance with the University's Policy Reporting a Potential Conflict of Interest or Conflict of Commitment in Research.

### Function

The Office of Research & Commercialization in conjunction with the University Compliance, Ethics, and Risk Office will review disclosures of outside activities, interests, and commitments. Disclosures containing actual or potential conflicts of interest in research will be reviewed by the FCOIC. The Committee will determine if a management plan or other action is necessary.

- Review disclosures of *significant financial interests* (SFI) in accordance with federal regulations.
  - Review and determine whether a SFI is related to the investigator's research. A SFI is related to the research when the interest could be affected by the research; or the SFI is in an entity whose financial interest could be affected by the research. Determine if the SFI is a financial conflict of interest (FCOI) that could directly and significantly affect the design, conduct, or reporting of the research.
  - Determine appropriate mitigation measures to manage or eliminate research related conflicts as necessary. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
    - Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
    - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
    - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
    - Modification of the research plan;
    - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
  - Severance of relationships that create financial conflicts.
- Review exemptions and monitoring plans for actual or potential conflicts of interest in accordance with state statutes. Determine if additional mitigation measures are necessary.
- Review monitoring plans in accordance with the University Employment of Relatives policy when research projects require unique skills or attributes of an individual that are not available in another candidate besides that of the employee's relative.
- Review annual updates or revisions to monitoring plans that indicate significant changes in financial interests or new sponsored research or technology agreements with the university.
- Report violations of monitoring plans to the Director of Compliance and provide recommendations regarding corrective or disciplinary actions as requested.
- Make recommendations to the Director of Compliance regarding COI policy and process decisions.
- Establish FCOIC guidelines and processes.

### **Composition and Structure**

Committee members are to represent a cross section of academic disciplines within the University. Committee members are appointed by the Vice President for Research and may serve 1-2 year terms with options for reappointment. Office of Research & Commercialization representatives may attend the meetings, but are not voting members of the FCOIC. The Committee is responsible for selecting a faculty chair and a faculty co-chair. The co-chair will serve as chair in the chair's absence. Chair responsibilities are as follows:

- Provide leadership and ensure Committee is aware of their obligations and responsibilities.
- Communicate with the Director of Compliance and Research Integrity Compliance.
- Ensure minutes are complete and accurate and reviewed by the Committee.
- Facilitate committee decision making and recommendation process.
- Officiate and conduct meetings
  - Call meeting to order.
  - Determine quorum.
  - Ensure that all items on the agenda are addressed.
  - Put motions to vote and announce the outcome.
  - Assist in the wording of motions upon request.
  - Call meeting adjournment.

Based on the need for specific expertise or impartial and objective insights, subject matter experts may be contacted to advise the committee or participate in Committee meetings and discussions when the FCOIC is considering conflict of interest issues or implementing mitigation measures. The Committee may engage directly with the investigator regarding the management plan.

### **Meetings**

Committee meetings are tentatively scheduled on a monthly basis and may be scheduled more or less frequently as needed. Email communication and electronic actions are utilized as the need arises. Meetings are documented through minutes and conducted in general accord with Robert's Rules of Order. A quorum must be present to conduct business in the name of the Committee. A quorum shall consist of a majority (more than half or more than 50%) of all voting Committee members. Participation by electronic technology is acceptable as specified by the FCOIC. Regular voting members are expected to join 75% (~8 out of 12) of scheduled meetings in person or electronically per appointment year. Alternate members may vote in place of absent voting member.

### **Training**

The *Conflict of Interest Mini-Course* through the online CITI program shall be completed by all members within 30 days of their appointment to the Committee. Additional training opportunities and materials may also be provided.

## **Confidentiality Requirements**

Committee members are required to sign and adhere to confidentiality requirements established under the FCOIC Confidentiality Agreement.

## **Recusal Due to Conflict of Interest**

Committee members with a conflict of interest that requires recusal from participating in committee actions shall notify the FCOIC Chair of the need to recuse themselves and not participate in decision making or voting. The conflicted FCOIC member may provide information requested by the FCOIC. Quorum is affected when a member is recused for a conflict of interest. The recusal and the absence of the conflicted member will be documented in the meeting minutes.

A FCOIC member is automatically considered to have a conflicting interest when the individual or the individual's immediate family have any of the following:

- Involvement in the design, conduct, or reporting of research related to the disclosed financial interest.
- Ownership interest, stock options, or compensation in/from the disclosed entity.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Any other reason for which the member or consultant believes that he or she cannot provide an objective review.

## **Support**

The Office of Research & Commercialization provides regulatory guidance. Committee recommendations or reports of non-compliance reported to the Director of Compliance will be presented by the Director of Compliance to the VP of Research as appropriate. The University Ethics, Compliance, Risk office may also be contacted for any support, guidance, or assistance with legal issues as needed by the Committee. The FCOIC is administratively supported by the Office of Research & Commercialization Research Integrity Compliance unit as follows:

- Coordinates meeting locations and times.
- Coordinates reviews conducted outside meetings as applicable.
- Prepares meeting documents including agenda, meeting minutes, and relevant review documents.
- Ensures the meeting agenda and relevant documents are circulated to the Committee.
- Communicates with disclosers, monitors, or subject matter experts regarding recommendations and actions requested by FCOIC.
- Conducts preliminary review of the COI disclosures and identifies disclosure records requiring review by the FCOIC.
- Researches and presents information relevant to the review process.
- Assists disclosers with preparation and performs preliminary review of monitoring plans, exemptions, and annual updates or revisions to monitoring plans prior to submission to the FCOIC.
- Provides guidance on federal regulations, state statutes, and institutional policies.
- Provides training and educational opportunities.

## **References**

- [Reporting a Potential Conflict of Interest or Conflict of Commitment in Research Policy 4.504.2](#)
- [Financial Conflict of Interest Guidelines/Office of Research & Commercialization](#)
- [Employment of Relatives Policy 3-008.2](#)
- [UCF-3.018 Conflict of Interest or Commitment; Outside Activity or Employment](#)
- [Code of Ethics for Public Officers and Employees - Florida Statutes, Title X, 112.313](#)
- [54.1-6 National Science Foundation Award and Administration Guide Chapter IV. Grantee Standards A. Conflict of Interest Policies](#)
- [DHHS-42 CFR Part 50, 45 CFR Part 94 Final Rule](#)
- [National Institutes of Health Financial Conflict of Interest](#)