

Financial Conflicts of Interest in Research

Research Compliance and Regulatory Affairs
Emory University



Mission: To Ensure Research Objectivity



The design, conduct, and reporting of research must be objective



Multifaceted relationships between Emory Investigators and industry often complement research



As stewards of federal money we must follow federal rules

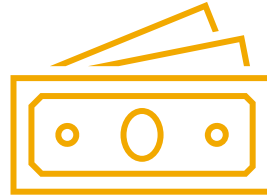



There is a primary commitment of time and intellectual energy owed to Emory by employees



What is a Financial Conflict of Interest?

A FCOI is the institutional determination that an Investigator or Key Personnel's Significant Financial Interest (SFI) could significantly alter the design, conduct, or reporting of research



 **EMORY UNIVERSITY** | Official University Policy
<https://emory.ellucid.com>

Policy 7.7

Policy for Investigators Holding a Financial Interest in Research

Responsible Official: VP for Research Administration
Administering Division/Department: Research Compliance
Effective Date: August 24, 2012
Last Revision Date: March 20, 2017

Policy Sections:

- I. Overview
- II. Applicability
- III. Policy Details
- IV. Definitions
- V. Related Links
- VI. Contact Information
- VII. Revision History



What is a Significant Financial Interest?

A SFI is one or more of the following financial interests held by an Investigator or Key Personnel, their spouse, or dependent children:

- Compensation or honoraria > \$5,000 from an entity*
- Ownership interests valued > \$5,000 in a publicly traded entity
- Ownership interests in a privately held entity (e.g., start-up companies, LLCs)
- Any intellectual property ownership, fees, and/or royalties
- Management positions in a non-Emory entity (e.g., director, officer, trustee, management employee)*
- Sponsored travel over \$5,000 within a 12-month period*

Within a 12-month period of the last disclosure



What is NOT a Significant Financial Interest?

- Salary or other compensation for services from Emory
- Compensation or honoraria from the US government, US institute of higher education, US academic teaching hospital and/or medical center, etc.
- Ownership interests from investment vehicles such as mutual funds and retirement accounts not controlled by the owner(s)
- Sponsored travel from Emory
- Gifts to Emory where the Investigator or Key Personnel has no signing authority for the Emory account



When is Disclosure Required?

- Annually
- At proposal submission
- At award set-up
- Within 30 days of discovering or acquiring (through purchase, marriage, or inheritance) a new SFI
- The institution revises its FCOI policy or procedures in any manner that affects the requirements of Investigators
- The Institution finds an Investigator not in compliance with the institution's FCOI policy or management plan

Participation in the research activity can only begin after the COI/COC office has made a FCOI determination

Who Must Disclose?

Emory Policy 7.7, Investigators Holding a Financial Interest in Research applies to Investigators, Key Personnel, and covered individuals who, in the course of their association with the University:

- Apply for or receive funding for research at Emory by grant, subgrant, contract, subcontract, cooperative agreement



What Happens After A SFI Disclosure?

Relatedness Determination

The COI/COC Office reviews the SFI to determine if there is a relation to the Investigator's research at Emory

FCOI Determination

If related, the COI/COC Committee reviews the SFI to determine if it is a FCOI or not

Management Determination

If the Committee determines there is a FCOI, management strategies will be implemented via a management plan



FCOI Management Strategies

- Disclosure to the research team
- Disclosure on all presentations, publications, and press releases
- Disclosure on all appropriate informed consent forms
- Disclosure on FDA forms
- Assignment of and reporting to an independent reviewer
- Change of role within the research study
- Restrictions that include but are not limited to:
 - obtaining and analyzing data
 - obtaining informed consent
 - Analyzing and reporting adverse events
 - Participation until the role identified as the conflict is eliminated



Q & A

