

Financial Conflict of Interest (FCOI) Policy

Purpose

This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants, cooperative agreements, and contracts will be free from bias resulting from Investigator financial conflicts of interest.

Scope

This policy applies to all Investigators (including subrecipient Investigators) planning to participate in, or participating in PHS funded research.

Definitions

Investigator

The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS.

Financial Interest

Anything of monetary value, whether or not the value is readily ascertainable.

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 and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. For publicly traded entities:
 - Value of compensation exceeding \$5,000 in 12 months
 - Any equity interest exceeding \$5,000
2. For non-publicly traded entities:
 - Value of compensation exceeding \$5,000 in 12 months
 - Any equity interest regardless of value
3. Intellectual property rights and interests upon receipt of income
4. Travel reimbursement/sponsorship exceeding \$5,000 from a single entity

Exclusions from SFI

- Salary or other remuneration from the Institution
- Income from investment vehicles such as mutual funds
- Income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education
- Income from service on advisory committees for government agencies or institutions of higher education

Disclosure Requirements

Initial Disclosure

All Investigators must disclose their SFIs:

- At the time of application for PHS-funded research
- Before joining an ongoing PHS-funded research project

Ongoing Disclosure

Investigators must submit:

- Annual disclosure of SFIs
- Updated disclosure within 30 days of discovering or acquiring new SFIs

Review and Management of Financial Conflicts of Interest

Review Process

1. The Institutional Official will review all financial disclosures
2. Determine whether any SFIs relate to PHS-funded research
3. Determine whether a financial conflict of interest exists
4. Develop and implement management plans as needed

Management Plans May Include

- Public disclosure of FCOIs
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in specific portions of the research
- Reduction or elimination of the financial interest

Reporting Requirements

The Institution will report FCOIs to PHS:

- Prior to expenditure of funds
- Within 60 days of identification of an Investigator participating in the project
- Annually during the period of award

Training Requirements

Investigators must complete FCOI training:

- Prior to engaging in research related to any PHS-funded grant
- At least every four years
- Immediately when:
 - This policy changes
 - An Investigator is new to the Institution
 - The Institution finds an Investigator noncompliant

Public Accessibility

This policy and information about identified FCOIs held by senior/key personnel will be publicly accessible via the institutional website.

Enforcement and Sanctions

Failure to comply with this policy may result in:

- Disciplinary actions
- Suspension of research activities
- Termination of employment
- Other sanctions as appropriate

Record Retention

Records of financial disclosures and actions taken will be maintained for at least three years from:

- The date of submission of the final expenditures report
- Other dates specified in 45 CFR 74.53(b) and 92.42(b)

Point of Contact

For questions regarding this policy, contact: Amit Lamba Email: amit@mangoes.ai, amitlamba@gmail.com

Effective Date

July 1, 2024

Last Updated: January 14, 2025