

Institute for Healthcare Improvement Financial Conflict of Interest (FCOI) Policy

Purpose: The purpose of this policy is to promote 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 or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Applicability: This policy applies to all individuals who participate in the design, conduct, or reporting of research funded by the PHS. This includes, but is not limited to, principal investigators, co-investigators, and any other person who is responsible for the design, conduct, or reporting of such research.

Definitions:

1. **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
2. **Significant Financial Interest (SFI):** Anything of monetary value, whether or not the value is readily ascertainable, that:
 - Exceeds \$5,000 in value (aggregated for the Investigator and the Investigator's spouse and dependent children) in the past 12 months.
 - Represents any equity interest in a non-publicly traded entity.
 - Represents any intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
3. **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.

Disclosure of Financial Interests: Investigators must disclose their significant financial interests (SFIs) to the Institution's designated official(s) no later than the time of application for PHS-funded research. Disclosures must be updated:

- Annually.
- Within 30 days of discovering or acquiring a new SFI.

Review and Management of Financial Conflicts of Interest:

1. **Review:** The Institution's designated official(s) will review all disclosures of SFIs to determine whether they constitute FCOIs.
2. **Management:** If an FCOI is identified, the Institution must develop and implement a management plan to address the conflict. This may include:
 - Public disclosure of the FCOI.
 - Monitoring of the research by independent reviewers.
 - Modification of the research plan.
 - Disqualification from participation in all or a portion of the research.
 - Divestiture of the SFI.
 - Severance of relationships that create the conflict.

Reporting of Financial Conflicts of Interest: The Institution must report identified FCOIs to the PHS Awarding Component prior to the expenditure of funds and within 60 days of identifying any new FCOI. The report must include:

- The nature of the FCOI.
- The value of the financial interest.
- A description of how the FCOI relates to the PHS-funded research.
- The key elements of the Institution's management plan.

Training: All Investigators must complete training on the Institution's FCOI policy and the PHS regulations prior to engaging in PHS-funded research and at least every four years thereafter. Training must also be completed immediately under the following circumstances:

- The Institution revises its FCOI policy in a manner that affects the requirements of Investigators.
- An Investigator is new to the Institution.
- The Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.

Non-Compliance: If an Investigator fails to comply with this policy or a management plan, the Institution must take corrective action and report the non-compliance to the PHS Awarding Component.

Record Retention: The Institution must maintain records of all Investigator disclosures of financial interests and the Institution's review and management of such disclosures for at least three years from the date of submission of the final expenditures report.