
Public Health Services (PHS) Requirements for Financial Disclosures and Conflict of Interest (COI) Policy for Social Changemakers and Innovators (SOCHAI)

I. General Policy and Purpose

Members of SOCHAI, including all Investigators, staff, and affiliates, must support SOCHAI's mission in a manner that prioritizes integrity, transparency, and accountability. SOCHAI requires disclosure of significant financial interests (SFIs) to prevent conflicts of interest (COIs) in PHS-funded research. This policy aligns with U.S. PHS regulations to prevent potential bias in research and protect the organization's integrity and commitment to transparency.

II. Scope

This policy applies to all SOCHAI Investigators participating in PHS-funded projects, including grants, cooperative agreements, and subawards. It mandates SFI disclosure, periodic training, and adherence to SOCHAI's COI management procedures.

III. Investigator Requirements

Investigators, including Project Directors (PD), Principal Investigators (PI), and collaborators, must:

1. Submit an SFI Disclosure Form at the time of application for PHS funding.
2. Update disclosures annually or within 30 days of discovering or acquiring new SFIs.
3. Complete Financial COI (FCOI) training at least every four years.

FCOI Training Requirements

The SOCHAI Compliance Department ensures all Investigators complete FCOI training before participating in PHS-funded projects. Training is also required upon:

1. Policy or procedure revisions that impact COI requirements,
2. Appointment of new PHS-funded Investigators, or
3. Instances of non-compliance with the policy.

IV. Disclosure Submission Procedures

The Office of Sponsored Projects (OSP) manages SFI disclosures. Investigators must submit an SFI Disclosure Form detailing SFIs, including those of their spouse/domestic partner and dependents, that relate to their SOCHAI responsibilities. Annual updates and disclosures within 30 days of new SFIs are required.

V. SFI Review and Management Process

The designated OSP official reviews all SFIs to determine their relevance to PHS-funded projects. If an FCOI is found, the OSP may implement a management plan or restrict project participation. Conditions for managing conflicts may include:

- Public disclosure of SFIs,
- Appointment of independent monitors,
- Adjustments to research design or personnel roles.

VI. Reporting to PHS

Prior to expanding PHS-awarded funds, SOCHAI submits FCOI reports on any identified conflicts, detailing:

- Project information and nature of financial interest,
- COI management plan and monitoring procedures.

Annual updates on FCOIs are also submitted to PHS, covering conflict status and management.

VII. Mitigation Reporting Due to Noncompliance

In cases of noncompliance, including failure to disclose SFIs or adhere to management plans, SOCHAI will conduct a retrospective review within 120 days to determine potential bias in the PHS-funded project. Key elements documented include:

- Project details, including PD/PI and Investigator with FCOI,
- Reasons for the review, methodology, findings, and conclusions.

If bias is detected, SOCHAI will:

1. Update the FCOI report and submit a mitigation report to PHS, including the impact of the bias and corrective actions.

2. Implement interim measures during the review period to maintain compliance.

VIII. Subrecipient Requirements

For PHS-funded research involving subrecipients, SOCHAI will determine if its COI policy or the subrecipient's COI policy applies. The subrecipient must certify compliance with 42 CFR Part 50, Subpart F. If certification is not possible, subrecipient disclosures will follow SOCHAI's COI policy. SOCHAI will report any subrecipient FCOIs to PHS before fund expenditures.

IX. Transparency and Confidentiality of Financial Disclosures

Transparency: In alignment with SOCHAI's commitment to transparency, this policy ensures clear public reporting of COI management. SOCHAI will make certain FCOI information publicly accessible, with updates provided annually or within 60 days for new disclosures.

Confidentiality: SOCHAI is committed to secure handling of all financial data, including SFI disclosures. Disclosures will be accessible only to authorized personnel and protected by confidentiality standards.

X. Segregation of Duties and Approval Authority

SOCHAI maintains strict segregation of duties to maximize accountability. The COI review, approval, and compliance monitoring involve multiple levels, with distinct personnel handling each responsibility. For all FCOI decisions, the SOCHAI President or a designated representative, alongside a compliance team member, must provide multi-level approval for effective conflict management.

XI. Financial Controls and Record-Keeping

Record Maintenance: Following SOCHAI's financial control standards, all COI-related financial documents, including disclosures, training records, and management plans, are maintained for at least five years. Secure storage and limited access ensure data protection and compliance with regulatory standards.

Periodic Reviews: COI procedures are reviewed quarterly or bi-annually, ensuring alignment with regulatory changes and SOCHAI's financial control practices.

XII. Procurement and Grant Management

Subrecipient Monitoring: Subrecipient COI compliance measures follow SOCHAI's procurement and subgrant review protocols, ensuring that subrecipients meet required standards.

Documentation and Audit: All agreements with subrecipients contain explicit terms for compliance with PHS COI requirements. COI compliance will be included in SOCHAI's annual financial audits, focusing on COI records and adherence to management plans.

XIII. Remedies, Enforcement, and Sanctions

In cases where noncompliance appears to bias PHS-funded research, SOCHAI will:

1. Notify PHS promptly of corrective actions,
2. Conduct a retrospective review,
3. Submit a mitigation report if required.

Violations may lead to disciplinary actions as outlined in SOCHAI's policies, including suspension of research privileges or financial accountability for policy violations.

Annual Audits: COI compliance will be integrated into SOCHAI's annual audits, reviewing COI management records, adherence to management plans, and any noncompliance remedies.

XIV. Clinical Research Disclosure Requirements

In cases where PHS-funded clinical research is biased due to an unmanaged FCOI, SOCHAI will:

1. Require the Investigator to disclose the FCOI in all public presentations,
2. Submit an addendum request for previously published results.

XV. Records and Public Access

SOCHAI will maintain all SFI Disclosure Forms, management plans, and training certifications for at least five years after final expenditures are submitted to PHS, in accordance with 42 CFR Part 50, Subpart F. The policy will be publicly accessible on SOCHAI's website, updated within 60 days for newly identified FCOIs.

Definitions and References

All terms follow definitions under SOCHAI's Financial Policy and relevant PHS regulations. SOCHAI will reference the NIH online tutorial on Financial Conflicts of Interest to fulfill FCOI training requirements.

Additional Information and Resources

1. Financial Conflicts of Interest, the National Institutes of Health, Office of Extramural

Research: [Financial Conflict of Interest | grants.nih.gov](https://www.grants.nih.gov/financial-conflict-of-interest/)