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Financial Conflict of Interest (FCOI) in Research, SY-AD-018

APPLIES TO

All Southern Illinois Healthcare (SIH) workforce members.

I. POLICY

Southern Illinois Healthcare (SIH) is committed to maintaining the highest standards of research integrity through transparency, objectivity, and ethical conduct. Research funded by the Public Health Service (PHS) and the National Institutes of Health (NIH) needs to be conducted free from bias that could arise from Financial Conflicts of Interest (FCOI).

This policy establishes clear expectations for the identification, disclosure, review, management, and reporting of Significant Financial Interests (SFIs) that could reasonably influence the design, conduct, or reporting of research activities. Through comprehensive oversight and proactive management, we ensure that financial considerations do not compromise the scientific merit or public trust in our research endeavors.

The policy aligns with federal requirements outlined in 42 CFR Part 50 Subpart F and 45 CFR Part 94, encompassing all responsibilities related to investigator training, financial disclosure, conflict review and management, regulatory reporting, public accessibility of information, and appropriate record retention.

II. DEFINITIONS

Investigator – Any individual who bears responsibility for the design, conduct, or reporting of PHS-funded research. This designation includes Principal Investigators, Co-Investigators, Sub-Investigators, key personnel, collaborators, and consultants who contribute substantively to the research.

Significant Financial Interest (SFI) – A financial interest that meets or exceeds the disclosure thresholds

established by PHS regulations and reasonably appears to be related to the investigator's institutional responsibilities. Examples include:

- Remuneration or equity interest from a single entity totaling more than $5,000 received during the twelve (12) months preceding the disclosure.
- Rights to intellectual property, including patents and royalties from such rights.
- Travel sponsored or reimbursed by external entities, excluding travel reimbursed by U.S. federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

Financial Conflict of Interest (FCOI) – A Significant Financial Interest that SIH determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Institutional Responsibilities – The professional duties an investigator performs on behalf of Southern Illinois Healthcare, including research activities, clinical care, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Subrecipient – An external individual or entity that receives a subaward from Southern Illinois Healthcare to carry out a portion of a PHS-funded research project. Subrecipients may include universities, hospitals, non-profit organizations, commercial entities, or other qualified institutions.

III. RESPONSIBILITIES

1. Investigators bear primary responsibility for compliance with all FCOI requirements. This includes completing mandatory training within prescribed timeframes, disclosing all Significant Financial Interests in a timely and accurate manner, adhering to all conditions of any management plans implemented by the institution, and ensuring that subrecipients and collaborators under their direction fulfill all applicable PHS-related FCOI obligations.
2. The Compliance Department, in collaboration with Research Administration and the Legal Department, is responsible for reviewing all SFI disclosures, determining whether disclosed interests constitute FCOIs, developing and implementing management plans when conflicts are identified, conducting retrospective reviews in cases of noncompliance, and submitting all required FCOI reports to NIH through the eRA Commons FCOI Module in accordance with regulatory timelines.
3. Subrecipients who receive funding to conduct a portion of PHS-funded research share responsibility for programmatic decision-making and need to comply with all PHS FCOI requirements. Subrecipients are required to either adopt this policy or certify that their own policy meets PHS requirements, and need to fulfill all disclosure and reporting obligations specified in the subaward agreement.

IV. EQUIPMENT/MATERIALS

1. SFI Disclosure Forms
2. FCOI training modules (NIH tutorial or SIH-equivalent program)

3. NIH eRA Commons FCOI Module
4. Management plan templates
5. Retrospective review templates
6. Subrecipient FCOI agreement language

V. PROCEDURE

1. Training Requirements

1. All investigators must complete FCOI training:
    A. Prior to engaging in any PHS-funded research activities
    B. At least every four (4) years thereafter
    C. Immediately upon any of the following circumstances:
        i. Revisions to this policy that affect investigator responsibilities
        ii. An investigator is found to be noncompliant with this policy or an assigned management plan
2. SIH accepts completion of the NIH FCOI tutorial or an institutionally approved equivalent training program.

2. Disclosure Requirements

1. Initial Disclosure
    A. Investigators are required to complete and submit an SFI Disclosure Form prior to participating in any PHS-funded project.
2. Annual Disclosure
    A. Investigators are required update their disclosures at least annually during the period of the award.
3. Updated Disclosure within 30 Days
    A. Investigators are required to disclose the existence of any newly acquired or discovered Significant Financial Interest within thirty (30) days of its acquisition or discovery.

3. Review and Determination

1. All SFI disclosures undergo review by the Compliance Department, Legal Department, and Research Administration.
2. The review process determines:
    A. Whether the disclosed financial interest is related to PHS-funded research
    B. Whether the financial interest constitutes a Financial Conflict of Interest
    C. Whether a management plan is necessary to address the conflict

3. SIH may seek external consultation or expert review when appropriate to ensure thorough evaluation.

4. Management of FCOI

1. When a Financial Conflict of Interest is identified, the institution will develop a written management plan. Management strategies may include, but are not limited to:
    A. Public disclosure of the financial conflict of interest
    B. Monitoring of research by independent reviewers
    C. Modification of the research plan or protocol
    D. Change of personnel or personnel responsibilities
    E. Reduction or elimination of the financial interest through divestiture
    F. Severance of relationships that create the financial conflict
2. Investigators are required to comply fully with all conditions and restrictions specified in the management plan.

5. Reporting to NIH

1. SIH submits FCOI reports to the NIH:
    A. Prior to the expenditure of any funds under a PHS-funded research project
    B. Within sixty (60) days of identification for any FCOI identified subsequent to the initial report
    C. Annually, for the duration of the project period, for any previously reported FCOI that remains managed
    D. Following a retrospective review to update a previously submitted report, if bias is found
2. All FCOI reports include the information elements required under 42 CFR 50.605(b)(3).

6. Retrospective Review and Mitigation

1. When an investigator fails to comply with this policy or a management plan, the institution conducts a retrospective review of the investigator's activities and the PHS-funded research project within one hundred twenty (120) days of the determination of noncompliance.
2. If the retrospective review determines that bias in the design, conduct, or reporting of PHS-funded research may have occurred, the institution will:
    A. Promptly notify the PHS Awarding Component and provide a mitigation report
    B. Submit an updated FCOI report to include remedial actions taken or to be taken
    C. Implement measures to eliminate or mitigate the effect of the bias
3. All records relating to investigator disclosures, the institution's review of and response to such disclosures, and all actions taken under this policy needs to be retained for at least three (3)

years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations, as outlined in the *Record Retention* (SY-HI-002) policy.

7. Subrecipient Requirements

1. When Southern Illinois Healthcare issues a subaward to carry out any portion of a PHS-funded research project, the subaward agreement must:
    A. Specify whether the financial conflicts of interest policy of Southern Illinois Healthcare or that of the subrecipient will apply to the subrecipient's investigators
    B. Establish the time period for the subrecipient to report all identified FCOIs to Southern Illinois Healthcare
    C. Provide information regarding all identified FCOIs to enable Southern Illinois Healthcare to fulfill its reporting obligations to the PHS Awarding Component

8. Public Accessibility

1. Southern Illinois Healthcare makes this policy publicly accessible through electronic posting on its website.
2. Upon request, SIH will respond to written requests for information concerning any Significant Financial Interest disclosed to the them that meets the criteria for a reportable FCOI, in accordance with federal regulations.

VI. DOCUMENTATION

1. SIH retains all documentation related to this policy for a minimum of three (3) years from the date of submission of the final expenditures report, or for such longer period as may be required by law, regulation, or contractual obligation.
2. Documentation subject to retention includes, but is not limited to: all investigator SFI disclosure forms, the institution's review and determination of whether disclosed financial interests constitute FCOIs, all management plans and related documentation, all retrospective reviews and mitigation reports, all FCOI reports submitted to PHS Awarding Components, records of training completion, documentation of subrecipient compliance, and records of public disclosure requests and institutional responses. All documentation needs to be maintained in accordance with applicable regulatory and organizational requirements.

VII. REFERENCES

1. 42 CFR Part 50 Subpart F: Promoting Objectivity in Research
2. 45 CFR Part 94: Responsible Prospective Contractors
3. NIH Grants Policy Statement
4. NIH Financial Conflict of Interest Tutorial and Resources

REPLACES

N/A

Approval Signatures

Step Description	Approver	Date
	Andrew Ziramba: Regulatory Coordinator	1/26/2026
	John Antes: President/CEO	1/26/2026
	John Daly: VP/GEN COUNSEL	1/26/2026
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Applicability

Southern Illinois Healthcare Corporate System