



AMERICAN SOCIETY OF NEPHROLOGY

FINANCIAL CONFLICT OF INTEREST POLICY APPLICABLE TO NATIONAL INSTITUTES OF HEALTH AWARDS

The Federal Public Health Service has implemented guidelines (42 CFR Part 50 Subpart F and 45 CFR Part 94) concerning the Advancement of Neutrality in Research. These guidelines outline the necessary steps for both individuals and organizations to foster impartiality in research activities funded by the Public Health Service (PHS) and the National Institutes of Health. These guidelines are applicable to all research endeavors supported by PHS and National Institutes of Health (NIH) grants, cooperative agreements, and research contracts (excluding Phase 1 grants from the Small Business Innovation Research or Small Business Technology Transfer programs), as well as to subawards originating from PHS-sponsored projects.

Definitions

Financial Conflict of Interest (FCOI): A substantial financial interest that has the potential to directly and significantly influence the planning, execution, or communication of research funded by the PHS or NIH.

Investigator: The individual leading the project as the project director (PD) or principal investigator (PI), along with any other individual, regardless of their official title or position, who holds responsibility for the planning, execution, or communication of research supported by the award, or those seeking funding for such research. This may encompass collaborators or consultants, for instance. The principal investigator/project director from ASN will assess the person's role and level of autonomy in performing the work to ascertain the individuals accountable for the research's design, execution, and reporting.

PHS: The Public Health Service under the U.S. Department of Health and Human Services, along with any divisions of the PHS to which relevant authority may be assigned, including the National Institutes of Health (NIH).

Significant Financial Interest (SFI):

(1) A financial interest that includes one or more of the following types of interests held by the investigator (as well as their spouse and dependent children) and that reasonably appear to be associated with the investigator's institutional responsibilities on behalf of ASN.

- Concerning any publicly traded entity, a significant financial interest arises if the total remuneration received from the entity in the 24 months before the disclosure, along with the value of any equity interest in the entity as of the disclosure date—when combined for the investigator, investigator's spouse, and dependent children—exceeds \$0. For purposes of this definition, remuneration encompasses salary and any payment for services not otherwise categorized as salary (e.g., consulting fees, honoraria, compensation for authored work). Equity interest encompasses any type of stock, stock option, or other form of ownership interest, as determined using public prices or other reasonable assessments of fair market value.
- Concerning any non-publicly traded entity, a significant financial interest exists if the cumulative remuneration received from the entity in the 24 months leading up to the disclosure exceeds \$0, or if the investigator (or their spouse or dependent children)

possesses any form of equity interest (such as stock, stock option, or other ownership interest).

- Pertaining to intellectual property rights and interests (such as patents and copyrights), a significant financial interest is established when income exceeding \$0 is received in connection with these rights and interests.

(i) The term significant financial interest does not encompass the subsequent categories of financial interests: Compensation, royalties, or other payments provided by ASN to the investigator in instances where the investigator currently holds employment or holds a distinct appointment with ASN.

(ii) Earnings originating from investment vehicles, like mutual funds and retirement accounts, if the investigator does not directly oversee the investment decisions pertaining to these vehicles.

(iii) Earnings from seminars, lectures, or educational engagements sponsored by a government agency situated within the United States (U.S.), a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

(iv) Compensation originating from service rendered on advisory committees or review panels for a government agency within the U.S., a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute associated with a U.S. institution of higher education.

(2) Investigators are required to report any instances of sponsored or reimbursed travel, both foreign and domestic. This pertains to travel paid for on the investigator's behalf and not repaid directly to the investigator, making the precise monetary value not immediately available. This disclosure should, at the very least, encompass the trip's purpose, the sponsor or organizer's identity, the destination, and the duration. The obligation for disclosure does not extend to travel sponsored or reimbursed by the following entities:

- U.S. federal, state, or local government agencies,
- U.S. institutions of higher education and research institutes affiliated with U.S. institutions of higher education.
- Academic teaching hospitals and medical centers

Foreign Financial Interests: Investigators are obligated to disclose all financial interests of foreign origin, which includes earnings from seminars, lectures, teaching engagements, service on advisory committees or review panels, and sponsored or reimbursed travel. This applies to financial interests received from foreign entities, including foreign institutions of higher education or foreign governments (encompassing local, provincial, or similar governments of other nations). Such disclosure is necessary when the income surpasses the threshold for reporting, such as income exceeding \$0.

Disclosure (Reporting Financial Interests)

Before submitting an application for funding to the NIH grantee, both the principal investigator and all other investigators associated with ASN are required to disclose their significant financial interests (SFIs), as well as those of their spouse and dependent children, as defined in the previous section, to the ASN designated official. Any new investigator who intends to join the project after the application's submission to NIH or during the project's execution must promptly and before their involvement, disclose their SFIs to the designated official.

For the duration of the NIH award, each investigator participating in research is obligated to provide an

updated disclosure of their SFIs at least annually. This updated disclosure should encompass any information that wasn't initially reported to ASN according to this policy or in subsequent disclosures of SFIs. This includes details about any financial conflicts of interest identified in a NIH-funded project, either directly as a NIH grantee or indirectly through a subaward. Additionally, the updated information should include any changes in previously disclosed SFIs, such as updates to the value of equity interests that were previously reported.

In cases where an investigator is involved in research under an NIH award, any new SFIs, including those related to reimbursed travel, need to be reported within 30 days of their discovery or acquisition. This includes instances such as obtaining new financial interests through means like purchase, marriage, or inheritance.

Review:

The designated official at ASN will conduct reviews of disclosures. The designated official will review any significant financial interest (SFI) that has been identified in a disclosure; these interests will be compared to each research award on which the investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a financial conflict of interest (FCOI) related to that research award.

Guidelines for Determining Financial Conflict of Interest

The designated official will determine whether an investigator's SFI is related to the research under a NIH award and, if so, whether the SFI is a financial conflict of interest. An investigator's SFI is related to the research under the NIH award when the designated official reasonably determines that the SFI: could be affected by the research conducted under the award; or is in an entity whose financial interest could be affected by the research. The designated official may involve the investigator in the determination of whether a SFI is related to the research supported by the award. A financial conflict of interest exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

In determining if an investigator's SFI is related to the research under a NIH award, and if so, whether the relationship creates a FCOI, the designated official considers the role of the investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the designated official may also consider the following factors:

- Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes.
- Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely.
- Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention).
- Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board.
- Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs).
- The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity).
- Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the discloser's technology, the amount of commercialization payments received by the investigator from that technology, both currently or in the future.
- The number and nature of relationships an investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts.
- Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI.

- Whether other scientific groups are independently pursuing similar questions.
- Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias.
- Whether the goal of the project is a comparative evaluation of a technology in which an investigator has a SFI.
- Whether the project involves a subaward to an entity in which the investigator has a SFI.

Management of Financial Conflicts of Interest Involving Significant Financial Interests

In cases where a financial conflict of interest arises, the designated official will assess appropriate strategies to address the situation. These strategies might include the investigator refraining from influencing decisions related to the conflicting entity, abstaining from external activities that could lead to conflicts, adapting the nature of the activity, or implementing oversight through a subcommittee. The aim is to avoid or manage the conflict in a way that minimizes undue bias. While making these determinations, the designated official will refer to the principles outlined in this policy. Additionally, they will consider factors such as the investigator's indispensable role in advancing the research, which is influenced by their unique expertise and qualifications.

In the presence of FCOIs, the designated official will mitigate bias by employing such strategies as:

- Recusing from decisions related to conflicting entities.
- Abstaining from relevant external activities.
- Activity modifying or monitoring activities by a subcommittee;

Measures for FCOI management include:

- Public disclosure in presentations and publications.
- Notifying participants in human subjects research.
- Appointing an independent monitor.
- Adjusting the research plan.
- Changing personnel roles or disqualifying involvement.
- Reducing or eliminating financial interests.
- Severing relationships causing conflicts.
- Establishing a data and safety monitoring board for human subjects research.
- Implementing double-blind conditions.
- Conducting work at multiple sites.
- Explicitly disclosing the conflict to team members.
- Providing annual progress reports to officials.
- Disclosing FCOIs in presentations.

Should a conflict be identified by the designated official, it will convey its determination and the devised methods for resolving or mitigating the conflict in written form to the concerned individual, the relevant principal investigator/project director, and the appropriate immediate supervisor. The designated official will maintain records of the disclosure and pertinent details for a minimum of three years. If monitoring is prescribed for the activity, the designated official will outline the specific monitoring procedures and required record-keeping.

Expenditures on an NIH award will only be authorized once the investigator complies with the policy's disclosure requirements and commits in writing to adhere to any necessary conflict of interest management plans determined by the designated official. The designated official will inform the NIH in writing about the presence and nature of a financial conflict of interest, as well as the steps taken to address it. No expenditures can occur until the FCOI is reported to NIH by the grantee, who will also inform ASN when expenses can be incurred.

The designated official will maintain records of investigator disclosures, their review, and responses to such disclosures, along with all actions taken under this policy. These records will be kept for at least three years from the date of submitting the final expenditures report or, if applicable, in accordance with specified dates outlined in 45 C.F.R. 75.361 for different scenarios.

Public Access to Financial Conflict of Interest Information

Before disbursing any funds from an NIH award, ASN will ensure public accessibility of information by responding in writing to any request within five business days. This information will pertain to disclosed significant financial interests (SFIs) that meet these three criteria:

- (i) The SFI is currently held by senior/key personnel, including the principal investigator (PD/PI) and others identified as senior key personnel in award documents submitted to the NIH grantee.
- (ii) ASN confirms the SFI's relevance to the funded research.
- (iii) ASN determines the SFI qualifies as a financial conflict of interest.

The information provided via a publicly accessible website or written response within five days will minimally include:

- (i) Investigator's name.
- (ii) Investigator's role in the research project.
- (iii) Name of the entity with the SFI.
- (iv) Nature of the SFI.
- (v) Approximate dollar value of the SFI in predefined ranges or a note if its value can't be readily determined.

If a publicly accessible website is used for disclosure, the posted information will be updated annually and within 60 days of receiving new SFI details that have not been previously disclosed. Information on an individual's SFI, as per policy limitations, will be available for a minimum of three years from the most recent update date, accessible through written requests or posted on ASN's public website.

Reporting of Financial Conflicts of Interest

Before utilizing funds from an NIH-funded award, ASN will submit a financial conflict of interest report to NIH, adhering to NIH regulations. This report will detail any investigator's identified significant financial interest that poses a conflict, along with confirmation of the investigator's commitment to and execution of the corresponding management plan.

Throughout the duration of the award, including any extensions, ASN will submit an annual FCOI report to NIH, outlining the FCOI's current status and any changes to the management plan.

In situations where a significant financial interest conflicting with the research emerges after the initial FCOI report during an ongoing NIH-funded project (such as when a new investigator joins), ASN will furnish a FCOI report to NIH within 60 days. This report will address the financial conflict of interest, confirm the implementation of a management plan, and ensure the investigator's agreement with the relevant plan.

Training Obligations

Every investigator must undergo training in ASN's financial conflict of interest policy applicable to NIH awards before participating in research linked to any NIH award. This training should be repeated at least once every four years. Additionally, immediate training is required under the following circumstances:

- ASN modifies this policy or associated procedures in a manner affecting investigator requirements (training must be completed as specified in communications about such changes).
- A new investigator joins ASN's research project under an NIH award (training before involvement is mandatory).
- An investigator is found to be non-compliant with this policy or a management plan issued under it (training within 30 days, as directed by the designated official).

For training fulfillment, ASN mandates its investigators to complete the National Institutes of Health's financial conflict of interest tutorial accessible at:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

This training aligns with the stipulations and expectations of this policy. Upon completion, all investigators are required to print a certification of completion, which should be retained for audit purposes.

Non-Compliance with ASN's Conflict of Interest Policy for NIH Funded Awards

In instances where a financial conflict of interest remains unidentified or inadequately managed, which includes situations like an investigator's failure to disclose a significant financial interest leading to an FCOI, ASN will take the following steps within 120 days:

- Conduct a retrospective review of the investigator's activities and the research project to identify any potential bias in research design, conduct, or reporting.
- Document the retrospective review following the guidelines outlined in 42 CFR 50.605d.
- Document ASN's conclusion regarding whether any research conducted during the period of investigator non-compliance with this policy or an FCOI management plan displayed bias in research design, conduct, or reporting.

If bias is discovered, ASN will promptly notify NIH and submit a mitigation report through the eRA Commons FCOI Module. This report will address the impact of the bias on the research project and ASN's planned steps or actions taken to rectify or alleviate the impact of the bias.

Subsequently, ASN will provide annual FCOI reports to NIH, following the regulatory framework and terms of the award agreement. Depending on the nature of the financial conflict of interest, ASN may determine that interim measures are necessary to address the investigator's participation in the research project between the identification of the FCOI and the completion of ASN 's independent retrospective review.

Clinical Research

In situations where HHS identifies a funded clinical research project aimed at assessing the safety or efficacy of a drug, medical device, or treatment, and this project's design, execution, or reporting is overseen by an investigator with an undisclosed or unmanaged financial conflict of interest, ASN will mandate the involved investigator reveal the financial conflict of interest in all public presentations of the research findings. Additionally, the investigator will be required to seek an addendum to any previously published presentations.

Subrecipient Compliance with Financial Conflicts of Interest

A subrecipient relationship occurs when federal funds are channeled from or through ASN to another entity that plays a substantial role in a PHS-funded research project and is accountable to ASN for program outcomes and compliance. Subrecipients, including collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, must adhere to ASN's terms and conditions. Consequently, ASN will ensure reasonable measures to confirm subrecipient investigators' compliance with federal FCOI regulations.

Within a written agreement, ASN will incorporate terms that outline whether ASN's FCOI policy or the subrecipient's institution's policy applies to the subrecipient investigator.

- If the subrecipient's policy applies, the subrecipient institution will certify its compliance with federal FCOI regulations and its alignment with the policy. If certification cannot be provided, the agreement will state the subrecipient investigator's adherence to ASN's FCOI policy for disclosing relevant significant financial interests.
- ASN will report FCOIs, if applicable, for subrecipient investigators to NIH through the eRA Commons FCOI module.

In cases where the subrecipient's conflict of interest policy applies:

- The agreement will specify a reporting period for the subrecipient to disclose identified FCOIs to ASN. This timeframe must allow timely FCOI reporting to NIH through the eRA Commons FCOI module.

For subrecipient investigators subject to ASN's investigator FCOI policy:

- The agreement will outline a reporting window for the subrecipient to submit all investigator SFI disclosures to ASN. This period will ensure ASN's compliance with review, management, and reporting obligations under the regulation.
- ASN will report NIH FCOI findings for subrecipient investigators via the eRA Commons FCOI module.

Maintenance of Records

Records of financial disclosures and any resulting action will be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 75.361 for different situations. ASN will retain records for each competitive segment as provided in the regulation.

Non-Compliance with This Policy

Expenditures of funds for an NIH-supported award will only proceed if the investigator has fulfilled the policy's disclosure prerequisites and has provided written consent to adhere to an approved FCOI management plan authorized by the designated official.

Point of Contact

If you encounter a conflict of interest, or if you have inquiries to discuss, please contact the ASN administrator at crichardson@asn-online.org