

SOCIETY FOR NEUROSCIENCE (SfN)
Financial Conflict of Interest Policy (FCOI)
for Public Health Service (PHS)-Supported Funding

Purpose of Policy

This Financial Conflict of Interest (FCOI) policy provides guidelines for identifying, disclosing, and managing significant financial conflicts of interest related to Public Health Service (PHS)-funded SfN programs. This policy is intended to meet or exceed requirements under the 2011 Revised Financial Conflict of Interest regulation, [42 CFR Part 50 Subpart F](#), "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."

This policy applies to each Investigator, as defined by the regulation, who is planning to participate in or is participating in PHS-funded SfN activities, including serving as a Principal Investigator (PI) or Co-Principal Investigator (Co-PI) on NIH-supported SfN grants. This policy outlines the administrative process for identifying FCOIs, promoting and enforcing Investigator compliance with the regulation, managing FCOIs, providing initial and ongoing FCOI reports, and making FCOI and Significant Financial Interest (SFI) information available to HHS.

SfN's Signing Official (SO) for PHS-supported activities serves as the Institutional Official for this policy and is responsible for ensuring the implementation of this policy. This policy operates in addition to other SfN Conflict of Interest policies by which SfN employees, Council, committee members, and other volunteers must abide.

Training ([42 CFR 50.604\(b\)](#))

For each new Investigator for any planned or actual PHS-funded SFN projects, the SfN Institutional Official will inform the Investigator of this FCOI policy, the federal regulation, and the Investigator's disclosure responsibilities. The Institutional Official will provide each Investigator with a copy of this policy and a FCOI Disclosure Form to complete, sign, and return to SfN.

Each PHS-supported Investigator will be required to complete training on this FCOI policy: (1) prior to engaging in research related to any PHS-funded grant; (2) at least every four years; and (3) immediately, if SfN revises its FCOI policy in such a way that affects Investigator requirements, if an Investigator is new to the SfN project, and/or if an Investigator is not in compliance with the policy or management plan.

Disclosure ([42 CFR 50.603](#), [42 CFR 50.604](#))

The Institutional Official will provide a SfN FCOI Disclosure Form to each Investigator. This Disclosure Form must be completed and signed by the Investigator: (1) no later than at the time of application for PHS-funded research, (2) at least annually during the period of the award; and (3) within 30 days of discovering or acquiring a new SFI.

Each Investigator must disclose any SFI, and those of the Investigator's spouse and dependent children, related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI outlined in [42 CFR 50.604\(e\)\(1\)-\(3\)](#):

(1) 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:

(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated,

exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Review ([42 CFR 50.604\(d\)\(f\)\(g\)](#), [42 CFR 50.605\(a\)\(1-4\)](#))

The Institutional Official or his/her designee will review all Investigator SFI disclosures and determine: (1) whether an Investigator's SFI is related to PHS-funded research; and (2) if so related, whether the SFI is an FCOI (*i.e.*, a SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research).

If the Institutional Official determines the FCOI can be managed, the Institutional Official will develop and implement a written management plan, intended to reduce or eliminate the conflict, as appropriate, within 60 days. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before participating or continuing participation in any related PHS-sponsored activity. The Institutional Official will monitor

Investigator compliance with the management plan until completion of the project.

If the Institutional Official determines the FCOI cannot be managed, the Institutional Official will move forward with suspension of the Investigator's association with the planned or actual PHS-supported project. The Institutional Official will provide the Investigator with a written explanation of this determination.

The above procedure also applies to cases where an Investigator discloses a new SFI or the Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution. The above review procedure also applies to any financial conflicts of a subrecipient Investigator.

Monitoring and Reporting ([42 CFR 50.604\(h\)](#), [42 CFR 50.605\(b\)](#)) [42 CFR 50.605\(a\)\(3\)\(iii\)](#))

The Institutional Official or his/her designee will submit initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for SfN and its subrecipients, if applicable, as required by the regulation:

- (1) Prior to the expenditure of funds.
- (2) Within 60 days of identification for an Investigator who is newly participating in the project.
- (3) Within 60 days for new, or newly identified, FCOIs for existing Investigators.
- (4) At least annually to provide the status of any FCOIs and any changes to the management plan, if applicable, until the completion of the project.
- (5) Following a retrospective review to update a previously submitted report, if appropriate.

The Institutional Official will notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and will submit a Mitigation Report in accordance with reporting elements required under [42 CFR 50.605\(a\)\(3\)\(iii\)](#). The Institution Official will also notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research ([42 CFR 50.606\(a\)](#)).

Maintenance of Records ([42 CFR 50.604\(i\)](#))

The Institution Official will ensure that all FCOI-related records are maintained at the Institution for at least three (3) years from the date the final expenditure report is submitted to the PHS (NIH) and/or from other dates specified in 45 CFR 75.361, where applicable.

Enforcement Mechanisms and Noncompliance ([42 CFR 50.604\(j\)](#), [42 CFR 50.605\(a\)\(3\)](#), [42 CFR 50.606\(c\)](#))

If an Investigator fails to comply with this policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other appropriate action taken by the Institutional Official. An Institutional Official's decision to suspend activities or take other action will be described in a written explanation of the decision to the Investigator and will notify the individual of the right to appeal the decision. The Institutional Official will promptly notify the PHS funding agency of action taken or to be taken.

If the Institutional Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI determined to be a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, the Institutional Official shall complete, within 120 days of this determination, a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research. The Institutional Official will update any previously submitted report to

the PHS relating to the research, specifying actions to be taken to manage the FCOI. If bias is found, the Institution will submit a Mitigation Report in accordance with PHS regulations. The Mitigation Report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project, and the plan of action to eliminate or mitigate the effect of the bias.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, the Institutional Official shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Violation of any part of this policy by SfN employees may also constitute cause for disciplinary or other administrative action pursuant to SfN policy.

Subrecipient Requirements (42 CFR 50.604(c))

In cases where a subrecipient Investigator is planned to participate in a PHS-funded SfN project, the Institutional Official will establish in a written agreement, whether the subrecipient will follow SfN FCOI policy or the FCOI policy of the subrecipient. If applicable, the Institutional Official will obtain a certification from the subrecipient that its FCOI policy complies with the regulation. If applicable, the Institutional Official will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a timeframe that allows SfN to report identified FCOIs to the NIH as required by the regulation. Alternatively, if applicable, the Institutional Official will include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the SfN to identify, manage and report identified FCOIs to the NIH.

Public Accessibility ([42 CFR 50.604\(a\)](#))

The Institutional Official or his/her designee will ensure that the Institution's FCOI policy is placed on the SfN website and publicly accessible. The Institutional Official or his/her designee will also ensure that available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), will be publicly accessible prior to the expenditure of funds. Per [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#), the information will:

- (1) Include the minimum elements as provided in the regulation.
- (2) Be posted on a public SfN website or made available within 5 calendar days of a written request.
- (3) Be updated, at least annually (website only but any response to a written request should include the updated information).
- (4) Be updated, within 60 days of a newly identified FCOI (website only but any response to a written request should include the updated information).
- (5) Remain available for three years from the date the information was most recently updated.