



**American Society  
for Neurochemistry**  
The Latest in Molecular and  
Cellular Neurobiology in the Americas

## **American Society for Neurochemistry Financial Conflict of Interest (FCOI) for Research Activities**

The American Society of Neurochemistry (“Society”) wants to ensure public trust in the integrity of any Society-sponsored research-related activities. To that end, the Society is committed to identifying and managing responsibly financial conflicts of interest (FCOI) to demonstrate research objectivity and compliance with federal regulations. The Society maintains this FCOI policy to meet its obligations under the Public Health Service’s (PHS) regulations (Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought) (“FCOI Regulations”). The FCOI Regulations are applicable to institutions that apply for or receive PHS1 grants or cooperative agreements for research and to each investigator (as defined below) planning to participate in or participating in such research.

### **Key Definitions**

Disclosure – an investigator’s disclosure of Significant Financial Interests and Outside Activities and Interests to the Society.

Institutional responsibilities – an investigator’s professional responsibilities on behalf of the Society, including research, research seminars, research consultation, clinical or other professional practice, participation in scholarly events, institutional committee memberships; and service on review panels.

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 (or a research conference) supported by a grant awarded to the Society.

Research – a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes conferences that seek to disseminate research as defined here and are to contribute to generalizable knowledge.

Senior/key personnel -the project director or principal investigator and any other person identified as senior/key personnel in the grant application, progress report or any other report submitted to the PHS.

Significant Financial Interest – means a financial interest – defined as anything of monetary value, may or may not be readily ascertainable – consisting of one or more of the interests of the investigator (and those of the investigator’s spouse and dependent children) that is related to the investigator’s institutional responsibilities. (See “Researchers Covered and Financial Interests that Must be Disclosed” for more detail.)

Signing Official – the person responsible for the procedures under this FCOI Policy but may designate one or more individuals to assist in any or all these responsibilities and/or may delegate any or all these responsibilities to one or more individuals.

PHS - The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component - The organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act - The statute codified at 42 U.S.C. 201 et seq.

### **Researchers Covered and Financial Interests that must be disclosed:**

Any investigator planning to or participating in PHS-funded research is required to disclose to the Society his/her known significant financial interests (and those of his/her spouse and dependent children) in one or more of the following areas:

Publicly Traded Entities – With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 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.

Privately Held Entities – 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 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock option or other ownership interest).

Intellectual Property – Intellectual property rights and interests (e.g., patents, copyrights), must be disclosed upon receipt of income (e.g., royalties) related to such rights and interests. The filing of any patent application also should be disclosed.

Travel Expenses – 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 in the 12 months preceding the disclosure if the value of such travel, when aggregated from all sources, exceeds \$5,000; 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. Disclosures relating to travel expenses must specify at a minimum the purpose and duration of the trip, the identity of the sponsor/organizer and the destination.

Exclusions – Significant financial interest does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by the Society to the investigator if the investigator is currently employed or otherwise appointed by the Society, including intellectual property rights assigned to the Society and agreements to share in royalties related to such rights
- income from investment vehicles, such as mutual funds and retirement accounts, if the investigator does not directly control the investment decisions made in these vehicles; and
- income from seminars, lectures or teaching engagements sponsored by, and 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.

### **Mandatory Investigator Training Requirements**

The Signing Official is responsible for ensuring that each investigator is informed about the Society's FCOI Policy, the investigator's responsibilities regarding disclosure of significant financial interests, and the FCOI regulations.

The Signing Official shall ensure that each investigator completes training prior to engaging in research related to any PHS-funded grant or cooperative agreement. Investigators are required to complete the FCOI training prior to engaging in PHS-supported research and at least every four years. Immediate training (provided as expeditiously as possible) is required when the investigator is new with the Society, is found to be noncompliant with the FCOI policy, and if there are any changes to the Society's FCOI policy.

### **Disclosure Requirements**

Prior to submission to PHS of an application for a research grant, the principal investigator shall identify to the Signing Official (1) investigators (as defined above) anticipated to be participating in the research, (2) those who are senior/key personnel (as defined below) and (3) those who are subrecipients and the institution(s) employing them.

Also prior to submission of the application, the Signing Official shall ensure that each investigator submits a listing of his/her known significant financial interests (as described above) and those of his/her spouse and dependent children that appear to be related to the investigator's institutional responsibilities, if any. The Signing Official shall ensure that subrecipient investigators either comply with this FCOI Policy or that their institution(s) provides assurances to enable the Society to fulfill the requirements of this FCOI Policy. In either case, the Signing Official shall ensure that the proper documentation as required under the FCOI Regulations is executed. Disclosure forms will be made available by the Society.

All disclosures must be updated annually during the period of the award or within 30 days of discovering or acquiring (e.g., through purchase, marriage, inheritance, or expansion of responsibilities) a new significant financial interest. The Signing Official shall ensure that annual update forms are sent to and promptly returned by each investigator. (One annual disclosure is sufficient to cover all ongoing PHS awards.) Each investigator is responsible for submitting disclosure forms within 30 days of discovering or acquiring a new significant financial interest. Disclosures shall be provided by an investigator at any other time upon request.

### **Review, Monitoring, and Reporting of FCOI Disclosures**

The Signing Official shall be responsible for tracking all the disclosure forms and reviewing with the Society's Executive Director the disclosure forms to make requisite determination and take any subsequent action.

Prior to the expenditure of funds or, with respect to an ongoing PHS-funded project, within 60 days of the disclosure or discovery of a significant financial interest, the Signing Official shall:

(1) review with the Society's Executive Director all disclosure forms and determine whether (a) an investigator's significant financial interest is related to PHS-funded research and (b) if so related, whether the significant financial interest is a financial conflict of interest (FCOI); and

(2) in the case of a FCOI, develop and implement a management plan specifying actions that have been and shall be taken to manage the FCOI; and

(3) submit initial and ongoing FCOI reports to the PHS Awarding Component as required under the FCOI Regulations [§50.605(b)(3), (4)].

An investigator's significant financial interest is related to PHS-funded research when the Signing Official and the Society's Executive Director determine that the significant financial interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. In determining whether an investigator's significant financial interest is related to PHS-funded research, the Signing Official and the Society's Executive Director will consider all relevant factors and information, including but not limited to whether there is an ongoing relationship between the investigator and the payer.

A FCOI exists when the Signing Official and the Society's Executive Director determine that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In determining whether there is an FCOI, the Signing Official and Society's Executive Director will consider all relevant factors and information, including but not limited to the nature of the research, the magnitude of the financial interest and degree to which it is related to the research, the extent to which the interest could be directly and substantially impacted by the research, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.

Prior to making the decision whether an FCOI exists, the Signing Official and the Society's Executive Director may impose interim measures, may ask the investigator to submit additional information and may meet or communicate with the investigator. The investigator may be encouraged to suggest procedures, protocols, or other measures designed to manage the FCOI to eliminate bias in the design, conduct and reporting of research.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research)
- For research involving human subjects, disclosure of financial conflicts to research participants
- Monitoring of the research by independent reviewers
- Modification of the research plan
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research
- Reduction or elimination of the financial interest and/or
- Severance of relationships that create such conflicts.

For all management plans, the Signing Official, in consultation with the Society's Executive Director, shall (i) monitor ongoing investigator compliance and (ii) submit annual updates to the PHS Awarding Component at the time and in the manner specified by the PHS Awarding Component, both until the completion of the PHS-funded research project to which the FCOI relates.

With respect to FCOI related to research sponsored by NIH, annual FCOI reports will be submitted through the eRA Commons FCOI Module for the duration of the project period (including extensions with or without funds) at the same time annual progress reports are required to be submitted and at the time of extension (if any).

If the FCOI is identified and eliminated prior to the expenditure of any PHS-awarded funds, no FCOI report need be submitted.

## **Maintenance of Records**

The Signing Official shall ensure that the Society maintains all disclosure forms and related records of determinations made and actions taken for a period of three years from the date of submission of the final expenditures report to the PHS (or, where applicable, from other dates specified in 45 CFR Part 75.361).

### **Enforcement Mechanism, Remedies, and Noncompliance**

All researchers to whom this FCOI Policy applies are expected to comply with it fully and promptly. The Society's Executive Director may impose sanctions for noncompliance which may include, but is not limited to, the following:

- Failure to make timely, full, or accurate disclosures
- Failure to provide information requested
- Failure to update a disclosure form as necessary or
- Failure to comply with a management plan.

For Society employees, sanctions may include denial of eligibility to engage in the research at issue or other appropriate penalties and include suspension or dismissal. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. The Signing Official and the Society's Executive Director will determine what sanctions, if any, are to be applied.

If an investigator has failed to comply with a management plan or, for whatever reason, an FCOI is one that was not identified, reviewed or managed in a timely manner, the Signing Official and the Society's Executive Director shall within 120 days of the determination of noncompliance conduct a retrospective review of the investigator's activities and the research project to determine whether any PHS-funded research or portion thereof conducted during the period of noncompliance was biased in design, conduct or reporting. The review shall be documented consistent with the FCOI Regulations [§60.605(a)(3)(ii)(B)]. The retrospective review will be documented and include the following elements:

- i. Project number
- ii. Project title
- iii. Name(s) of project director or principal investigator
- iv. Name of the investigator or key personnel with the FCOI
- v. Name of the entity with which the investigator or key personnel has a FCOI
- vi. Reason(s) for the retrospective review
- vii. Detailed methodology of the review process, composition of the review panel and the documents reviewed
- viii. Findings of the review and
- ix. Conclusions of the review

If a bias is found during the course of the review, the Signing Official and the Society's Executive Director will promptly notify the PHS Awarding Component (which may take its own action and/or require further action by

the Society and/or the investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations [§60.605(a)(3)(iii)]. If appropriate, the Signing Official will update the previously submitted FCOI report. In any event, the Signing Official, in consultation with the Society's Executive Director, shall submit FCOI reports annually thereafter.

For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS- funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the investigator shall disclose the FCOI in each public presentation of the results of the research (such as articles, manuscripts and oral presentations) and the Society shall request an addendum to previously published presentations.

### **Subrecipient**

When proposed Society research is to be funded by PHS and carried out through a subrecipient, the Society will establish in writing, at the time of proposal submission, whether this policy, or that of the subrecipient will apply to the subrecipient's Investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that the Society is able to meet its reporting obligations to the PHS awarding agency.

### **Public Accessibility Requirements**

The Society's FCOI Policy will be posted on a publicly accessible page of the Society's website, as required by the FCOI Regulations.

Prior to expending any funds under a PHS-funded grant or cooperative agreement, the Society shall ensure public accessibility to information concerning an FCOI held by a senior/key personnel member by providing a written response to any written request, such response to be postmarked or dated (if replying by electronic means) within five (5) business days of the receipt of the written request. Such information shall consist of that required to be provided under the FCOI Regulations [§50.605(a)(5)(ii), (iii)], shall be updated at least annually and within 60 days of the receipt or identification of information concerning an additional significant financial interest, and shall remain available for three years from the date the information was most recently updated. The Society shall also provide disclosures to other federal agencies or entities, as requested and if necessary for compliance with this FCOI policy or law.

**2022**